# PHARMACEUTICAL SUPPLY CHAIN SECURITY

## HEARING

BEFORE THE

SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY, AND HUMAN RESOURCES

OF THE

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

JULY 11, 2006

**Serial No. 109–227**

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

34–446 PDF WASHINGTON : 2007

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

## COMMITTEE ON GOVERNMENT REFORM

TOM DAVIS, Virginia, *Chairman*

CHRISTOPHER SHAYS, Connecticut
DAN BURTON, Indiana
ILEANA ROS-LEHTINEN, Florida
JOHN M. MCHUGH, New York
JOHN L. MICA, Florida
GIL GUTKNECHT, Minnesota
MARK E. SOUDER, Indiana
STEVEN C. LATOURETTE, Ohio
TODD RUSSELL PLATTS, Pennsylvania
CHRIS CANNON, Utah
JOHN J. DUNCAN, JR., Tennessee
CANDICE S. MILLER, Michigan
MICHAEL R. TURNER, Ohio
DARRELL E. ISSA, California
JON C. PORTER, Nevada
KENNY MARCHANT, Texas
LYNN A. WESTMORELAND, Georgia
PATRICK T. MCHENRY, North Carolina
CHARLES W. DENT, Pennsylvania
VIRGINIA FOXX, North Carolina
JEAN SCHMIDT, Ohio
BRIAN P. BILBRAY, California

HENRY A. WAXMAN, California
TOM LANTOS, California
MAJOR R. OWENS, New York
EDOLPHUS TOWNS, New York
PAUL E. KANJORSKI, Pennsylvania
CAROLYN B. MALONEY, New York
ELIJAH E. CUMMINGS, Maryland
DENNIS J. KUCINICH, Ohio
DANNY K. DAVIS, Illinois
WM. LACY CLAY, Missouri
DIANE E. WATSON, California
STEPHEN F. LYNCH, Massachusetts
CHRIS VAN HOLLEN, Maryland
LINDA T. SANCHEZ, California
C.A. DUTCH RUPPERSBERGER, Maryland
BRIAN HIGGINS, New York
ELEANOR HOLMES NORTON, District of Columbia

BERNARD SANDERS, Vermont
(Independent)

DAVID MARIN, *Staff Director*
LAWRENCE HALLORAN, *Deputy Staff Director*
TERESA AUSTIN, *Chief Clerk*
PHIL BARNETT, *Minority Chief of Staff/Chief Counsel*

### SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY, AND HUMAN RESOURCES

MARK E. SOUDER, Indiana, *Chairman*

PATRICK T. MCHENRY, North Carolina
DAN BURTON, Indiana
JOHN L. MICA, Florida
GIL GUTKNECHT, Minnesota
STEVEN C. LATOURETTE, Ohio
CHRIS CANNON, Utah
CANDICE S. MILLER, Michigan
VIRGINIA FOXX, North Carolina
JEAN SCHMIDT, Ohio

ELIJAH E. CUMMINGS, Maryland
BERNARD SANDERS, Vermont
DANNY K. DAVIS, Illinois
DIANE E. WATSON, California
LINDA T. SANCHEZ, California
C.A. DUTCH RUPPERSBERGER, Maryland
MAJOR R. OWENS, New York
ELEANOR HOLMES NORTON, District of Columbia

EX OFFICIO

TOM DAVIS, Virginia
HENRY A. WAXMAN, California

MARC WHEAT, *Staff Director*
MICHELLE GRESS, *Counsel*
KIMBERLY CRASWELL, *Clerk*
TONY HAYWOOD, *Minority Counsel*

# CONTENTS

# PHARMACEUTICAL SUPPLY CHAIN SECURITY

**TUESDAY, JULY 11, 2006**

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY,
AND HUMAN RESOURCES,
COMMITTEE ON GOVERNMENT REFORM,
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10 a.m., in room 2154, Rayburn House Office Building, Hon. Mark E. Souder (chairman of the subcommittee) presiding.

Present: Representatives Souder, Gutknecht, Foxx, Cummings, Ruppersberger, and Norton.

Staff present: Marc Wheat, staff director and chief counsel; Michelle Gress, counsel; Scott Springer, congressional fellow; Kimberly Craswell, clerk; Tony Haywood, minority counsel; and Jean Gosa, minority assistant clerk.

Mr. SOUDER. The subcommittee will come to order. Mr. Cummings is going to be a little late, and we will have Members in and out, but I want to get the hearing started on time.

Good morning, and thank you for being here today. This is the second hearing conducted by the subcommittee to investigate the threat of counterfeit drugs within the United States.

Today's hearing is focused on measures to prevent counterfeits from entering the pharmaceutical supply chains and to improve supply chain security. This hearing comes in the wake of FDA's recent update from its Counterfeit Drug Task Force which recommends ending the multi-year stay on implementing the pedigree rule required in the Prescription Drug Marketing Act, an act that was signed into law in 1988.

A pedigree shows the drug's chain of custody, tracking the product as it flows through the supply chain. States such as California and Florida already have tough pedigree laws, and other States are moving forward with their own legislation. The FDA's decision to implement the pedigree requirement is a welcome, if overdue, effort in the national fight against counterfeit medicines in a pharmaceutical supply chain.

Pedigrees can be paper or electronic, also known as an ePedigree; ePedigree can be accomplished through what is known as radio frequency identification [RFID], where a small RFID tag on the drug package is read and tracked from seller to seller providing, an electronic record of all transactions for the drug. Nonetheless, the pedigree is only one tool in the tool box for creating and maintaining a secure supply chain.

Counterfeit pharmaceutical drugs are illegal, generally unsafe and pose a serious threat to the public health. Moreover, despite some sensational media segments on the prevalence and danger of counterfeit drugs, the American public is generally unaware of the program.

The illegitimate business of creating, distributing and selling counterfeit pharmaceutical products is an unregulated, criminal and growing part of the global economy. There is one major difference between pharmaceutical counterfeiting and other underground industries: lives are at stake. It has been estimated that, globally, counterfeit pharmaceutical commerce will grow to become 16 percent of the aggregate size of the legitimate industry, a 6 percent increase from 2004. This illegal business will generate $75 billion in revenue in 2010, a 92 percent increase from 2005.

The counterfeit industry is also growing at a much faster rate than the legitimate pharmaceutical business. Some estimates indicate that counterfeit drug sales will grow 13 percent annually through 2010, compared to just 7.5 percent estimated annual growth for global pharmaceutical commerce.

Many of the products sold via drug traffickers contain ingredients that could be harmful, and these products are coming from illegal operations with very poor controls. The U.S. supply chain has become increasingly vulnerable to a variety of threats. Counterfeit drugs often travel through a distribution network of wholesalers, distributors, pharmacies, online shelf companies and criminal organizations buying, selling and reselling through unofficial channels with little product integrity. The FDA has confirmed that the large majority of known instances of counterfeit drugs have entered the supply stream through what is known as a secondary market, where drug diversion takes place. Drug diversion is the principle method by which counterfeits consistently enter the legitimate drug market. This happens because the pharmaceutical supply chain is not regulated by any single entity, private or governmental. The pharmacies within the State are monitored by the State Boards of Pharmacy which enforce the standards of care within each State. However, the State Boards of Pharmacy lack police power, and many are limited to only a handful of inspectors. Drug manufacturers have to comply with the FDA for the safety, effectiveness and labeling of their drugs. The drug manufacturers typically exercise no control over their drugs once they are shipped out of the manufacturing facility. Rather, the drugs are bought and sold by distributors and frequently pass in and out of the secondary market, where they may be bought and sold dozens of times, passed among several hands, repackaged, mishandled or relabeled.

Distributors like retailers and physicians are licensed by the States which must only meet the minimal standards set by the Prescription Drug Marketing Act. In order to obtain a distributor's license, some States' licensing requirements are more lenient than others. Although some States have toughened their licensing standards for distributors, this leaves a patchwork of inconsistent standards across the country. Unscrupulous distributors can exploit the lowest standards of some States to insert counterfeit or adulterated product in the legitimate drug supply chain.

When unscrupulous middlemen resell pharmaceuticals, they sometimes relabel them to reflect higher and more valuable doses, mishandle them to contaminate or degrade the drug, or substitute fake products for the legitimate goods. The counterfeits can be indistinguishable from the legitimate product. For the patient, there is no commercial transaction like this. The patient has virtually zero ability to inspect the drug's packaging or compare it to other samples. The patient who goes to a pharmacy to have his or her prescription filled is as helpless in determining the quality of the drug and completely dependent on a system that has experienced some tragic breaches. Moreover, it is impossible to measure the scope of the problem, and we cannot say with any degree of certainty how many or which counterfeit drugs make it to the pharmacy shelves because a health indication or ultimate death may be attributed to the patient's underlying illness rather than the drug.

I look forward to hearing from our witnesses an assessment of the current threats and available protective measures to strengthen the supply chain.

Our first panel today consists of Mr. Randall Lutter, Associate Commissioner for Policy and Planning at the Food and Drug Administration; and Mr. Kevin Delli-Colli, Deputy Assistant Director, Financial and Trade Investigations, Division, Office of Investigations, U.S. Immigration and Customs Enforcement [ICE].

Our second panel consists of Carmen Catizone, executive director of the National Association of the Boards of Pharmacy; Ms. Susan Winckler, vice president of policy and communications at the American Pharmacists Association; Mr. John Gray, president and CEO of Healthcare Distribution Management Association [HDMA]; Rick Raber, project manager with Northern APEX-RFID and a fellow Hoosier from northeastern Indiana.

Welcome to each of you, and I look forward to your testimony.

Mr. Gutknecht, do you have an opening statement?

[The prepared statement of Hon. Mark E. Souder follows:]

# Subcommittee on Criminal Justice, Drug Policy and Human Resources

## Opening Statement of Chairman Mark Souder

## "Pharmaceutical Supply Chain Security"

## July 11, 2006

Good morning, and thank you for being here today. This is the second hearing conducted by the Subcommittee to investigate the threat of counterfeit drugs within the United States. Today's hearing is focused on measures to prevent counterfeits from entering the pharmaceutical supply chain, and to improve supply chain security.

This hearing comes in the wake of the FDA's recent update from its Counterfeit Drug Task Force, which recommends ending the multi-year stay on implementing the "pedigree" rule required in the Prescription Drug Marketing Act, an Act that was signed into law in 1988. A pedigree shows the drug's chain of custody, tracking the product as it flows through the supply chain. States such as California and Florida already have tough pedigree laws, and other states are moving forward with their own legislation.

The FDA's decision to implement the pedigree requirement is a welcome – if overdue – effort in the national fight against counterfeit medicines in the pharmaceutical supply chain. Pedigrees can be "paper," or electronic, also known as e-pedigree. E-pedigree can be accomplished through what is known as Radio Frequency Identification, or RFID, where a small RFID "tag" on the drug package us read and tracked from seller to seller, providing an electronic record of all transactions for the drug. Nonetheless, the pedigree is only one tool in the toolbox for creating and maintaining a secure supply chain.

Counterfeit pharmaceutical drugs are illegal, generally unsafe, and pose a serious threat to the public health. Moreover, despite some sensational media segments on the prevalence and danger of counterfeit drugs, the American public is generally unaware of the problem. The illegitimate business of creating, distributing, and selling counterfeit pharmaceutical products is an unregulated, criminal and growing part of the global economy. There is one major difference between pharmaceutical counterfeiting and other underground industries: lives are at stake.

It has been estimated that globally, counterfeit pharmaceutical commerce will grow to become 16% of the aggregate size of the legitimate industry, a six percentage-point increase from 2004.[1] This illegal business will generate $75 billion in revenues for its owners in 2010, a 92% increase from 2005.[2]

The counterfeit industry is also growing at a much faster rate than the legitimate pharmaceutical business. Some estimates indicate that counterfeit drug sales will grow 13% annually through 2010, compared to just 7.5% estimated annual growth for global pharmaceutical commerce.[3] Many of the products sold via drug traffickers contain ingredients that could be harmful, and these products are coming from illegal operations with very poor controls.

The U.S. drug supply chain has become increasingly vulnerable to a variety of threats. Counterfeit drugs often travel through a distribution network of wholesalers, distributors, pharmacies, online shell companies, and criminal organizations buying, selling and re-selling through unofficial channels with little product integrity.

The FDA has confirmed that the large majority of known instances of counterfeit drugs have entered the supply stream through what is known as the secondary market, where drug diversion takes place. Drug diversion is the principal method by which counterfeits consistently enter the legitimate drug market.

This happens because the pharmaceutical supply chain is not regulated by any single entity, private or governmental. The pharmacies within a state are monitored by the state Boards of Pharmacy, which enforces the standards of care within each state. However, the state Boards of Pharmacy lack police power, and many are limited to only a handful of inspectors.

Drug manufacturers have to comply with the FDA for the safety, effectiveness, and labeling of their drugs. But drug manufacturers typically exercise no control over their drugs once they are shipped out of the manufacturing facility. Rather, the drugs are bought and sold by distributors, and frequently pass in and out of the secondary market, where they may be bought and sold dozens of times, passed among several hands, repackaged, mishandled, or relabeled.

Distributors, like retailers and physicians, are licensed by the states, which must only meet the minimal standards set by the Prescription Drug Marketing Act. In order to obtain a distributor's license, some states' licensing requirements are more lenient than others. Although several states have toughened their

---

[1] Peter Pitts, *21st Century Health Care Terrorism: The Perils of International Drug Counterfeiting*, Pacific Research Institute, Sept. 20, 2005.
[2] Id.
[3] Id.

licensing standards for distributors, this leaves a patchwork of inconsistent standards across the country; unscrupulous distributors can exploit the lower standards of some states to insert counterfeit or adulterated product into the legitimate drug supply chain.

When unscrupulous middle-men resell pharmaceuticals, they sometimes re-label them to reflect higher (and more valuable) doses, mishandle them to contaminate or degrade the drug, or substitute fake products for the legitimate goods. The counterfeits can be indistinguishable from legitimate product.

For the patient, there is no commercial transaction like this. The patient has virtually zero ability to inspect the drugs' packaging, or compare it to other samples. The patient who goes to a pharmacy to have his or her prescription filled is helpless in determining the quality of the drug, and completely dependant on a system that has experienced some tragic breaches. Moreover, it is impossible to measure the scope of the problem, and we cannot say with any degree of certainty how many, or which, counterfeit drugs make it to the pharmacy shelves because a health indication, or ultimate death, may be attributed to a patient's underlying illness rather than the drug.

I look forward to hearing from our witnesses an assessment of the current threats and available protective measures to strengthen the supply chain.

Our first panel today consists of Mr. Randall Lutter, Associate Commissioner for Policy and Planning at the Food and Drug Administration; and Mr. Kevin Delli-Colli, Deputy Assistant Director, Financial and Trade Investigations Division, Office of Investigations, with the U.S. Immigration and Customs Enforcement.

Our second panel consists of Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy; Ms. Susan C. Winckler, Vice President of Policy and Communications, for the American Pharmacists Association; Mr. John Gray, President and CEO, Healthcare Distribution Management Association (HDMA); and Mr. Rick Raber, Project Manager with Northern Apex – RFID, and a fellow Hoosier.

Welcome to each of you and I look forward to your testimony.

Mr. GUTKNECHT. Mr. Chairman, I don't so much have an opening statement, I just want to thank you and congratulate you for holding this hearing. This is an issue that I've had an interest in for a long time. It all started—this opening statement may get a little longer than I originally intended, but I want to just make a few points.

First of all, it started at a town hall meeting that I had many years ago where seniors began to question why it was they were treated like common criminals for buying their prescription drugs from Canada. And the argument that has been consistently proposed by the FDA and their fellows in the pharmaceutical industry is that we cannot guarantee the safety of drugs coming in from industrialized countries like Canada. The truth of the matter is, there is technology available today at low cost, and I've got some examples that I brought with me if you want to see audio visuals. In here, I have 50 RFID computer chips, and you can barely see them. But this technology is not futuristic. It's not pie-in-the-sky. It is available today. And we have the ability to protect the integrity and the safety of the drug supply not only here in the United States but from other industrialized countries. And so I think this hearing is a very important step I think on that path toward making certain that the pharmaceutical drugs that Americans take are safe but, more importantly, more affordable for all Americans.

So I really do want to thank you for having this hearing, and I'm delighted to be here.

Mr. SOUDER. I thank the gentleman. He's been very active and outspoken on this for some time, and I'm glad we can continue to progress with this.

I ask unanimous consent that all Members have 5 legislative days to submit written statements and questions for the hearing record, and any answers to written questions provided by the witnesses also be included in the record. Without objection, so ordered.

I also ask unanimous consent that all exhibits, documents and other materials referred to by Members may be included in the hearing record, that all Members be permitted to revise and extend remarks. Without objection, it's so ordered.

As the witnesses know, it's our standard procedure to ask witnesses to testify under oath. If you will raise your right hands, I will administer the oath to you.

[Witnesses sworn.]

Mr. SOUDER. Let the record show that both of the witnesses responded in the affirmative.

We thank you for coming today.

Dr. Lutter, is that correct? Did I say that correct? I look forward to your testimony. I'll have you start.

## STATEMENTS OF RANDALL W. LUTTER, ACTING ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG ADMINISTRATION; AND KEVIN DELLI-COLLI, DEPUTY ASSISTANT DIRECTOR, FINANCIAL AND TRADE INVESTIGATIONS DIVISION, OFFICE OF INVESTIGATIONS, U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT

### STATEMENT OF RANDALL W. LUTTER

Mr. LUTTER. Good morning, Chairman Souder, members of the subcommittee. I'm Dr. Randy Lutter, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration. Thank you for the opportunity to testify about FDA's efforts regarding counterfeit prescription drugs.

Counterfeit drug products and illicit drug diversion are major concerns to FDA. While the U.S. drug supply is among the safest in the world, we believe threats from drug counterfeiters have become increasingly sophisticated. Organizations and individuals who peddle fake medicines put unsuspecting patients at risk by exposing them to unknown contaminants and denying them medicines known to be safe and effective at treating their medical ailments.

Our mission is to protect and promote the public health, and today I will discuss measures FDA has taken and continues to take to fight phony medicines.

First I'd like to clarify what FDA considers counterfeit. The definition in the True Drug and Cosmetics Act focuses on fraud and deception toward the consumer as when persons falsely believe they are receiving a genuine FDA-approved product. It generally does not include products that are marketed as being similar to or a foreign version of an FDA-approved drug. Those types of products are also illegal but referred to as unapproved new drugs, not counterfeit drugs.

My written statement contains details of FDA's enforcement efforts to combat prescription drug counterfeiters; today, however, I'd like to highlight some of the work of FDA's Counterfeit Drug Task Force, and some of the recommendations made in the recently issued 2006 report.

The Task Force was established in 2003 and consists of senior FDA officials. Our mission is to develop recommendations for steps that FDA, other government agencies and industry could take to minimize the risk to the public from the introduction of counterfeit drugs into the U.S. distribution system.

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs. This framework called for a multi-layered approach to address the problem and stated among other things that widespread use of electronic track-and-trace technology would help secure the integrity of the drug supply chain by providing an accurate drug pedigree, which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy. Radio frequency identification is a promising technology to achieve electronic pedigree.

The third conclusion was that widespread adoption and use of electronic track-and-trace technology would be feasible by 2007. And finally, the effective date of certain regulations related to the

implementation of the Prescription Drug Marketing Act should be delayed until December 1, 2006, to give stakeholders in the supply chain time to focus on implementing widespread use of ePedigree.

In 2005, the Task Force issued an updated report which assessed FDA's and industry's progress toward implementing the 2004 recommendation. The Task Force found, among other things, that progress had been made in many areas, but progress toward widespread use of ePedigree was slowing, and the goal might not be met by 2007. This year, to evaluate progress toward widespread use of ePedigree by 2007 and to solicit public comment on the implementation of certain PDMA related regulations, we held a public meeting on February 8th and 9th. Subsequently, on June 9th, the Task Force issued its most recent report based on this extensive fact-finding effort. I'll focus my discussion on this 2006 report on the status of the stayed provisions related to PDMA and electronic track-and-trace technologies.

As you know, FDA published five regulations related to the PDMA in December 1999. The provisions in those regulations define the phrase "ongoing relationship" as used in the definition of authorized distributor of record set forth in the requirements regarding pedigrees and define the fields of information that must be included in the pedigree.

FDA had delayed the effective date for these provisions several times because of significant issues raised by stakeholders. Based on our recent fact-finding effort, we can no longer justify continuing the stay. A large majority of supply chain stakeholders told FDA that the regulations should be allowed to go into effect. Allowing the stay to expire will provide clarity in the prescription drug supply chain by distinguishing clearly authorized distributors of records who are exempt from providing drug pedigrees from non-authorized distributors of record, who must provide a pedigree.

While the regulations do not provide for a phased in approach for pedigree implementation, FDA has issued a draft compliance policy guidance for public comment that reflects the risk-based approach that FDA will use to focus its enforcement efforts regarding the pedigree regulations. The focus will be on prescription drug products that are most vulnerable to counterfeiting diversion based on factors such as high value, prior history of counterfeiting or diversion, reasonable likelihood of counterfeiting for new drugs, and other violations of law.

The 2006 report also states that FDA continues to believe that RFID is the most promising technology for implementing electronic track-and-trace in the prescription drug supply chain and that stakeholders should move quickly to implement this technology. FDA recognizes that implementing an RFID-enabled drug supply chain is challenging and urges manufacturers to take a risk-based approach to implementation.

The 2006 report also considered several technical issues related to adoption of electronic track-and-trace technology that were perceived as obstacles to implementation and are in need of resolution. These include mass serialization and unique identification of each drug package, universal pedigree, covering all drugs from all manufacturers to the dispenser, national uniform information, and privacy issues and the need for consumer education about RFID and

the labelling of RFID tag drug products in order to help prevent unauthorized disclosure of personal information.

FDA's vision of a safe and secure prescription drug supply chain is based on transparency and accountability for all persons who handle the prescription drug throughout the supply chain. With the pedigree regulations taking effect in December 2006, FDA expects that supply chain stakeholders will move quickly to electronic track-and-trace technology. Ultimately, we believe that the public health would be better protected if all stakeholders work cooperatively to enable all distributors to pass pedigrees.

FDA is doing its part to effectively enforce the law in conjunction with other Federal, State and local entities, to protect Americans from criminals who attempt to undermine the public health by introducing counterfeit and diverted prescription drugs into the U.S. drug supply.

I'd like to thank the subcommittee for the opportunity to testify today on this important issue. I'd be pleased to respond to any questions.

[The prepared statement of Mr. Lutter follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

**Statement of**

**Randall W. Lutter, Ph.D.**

**Associate Commissioner for Policy and Planning**
**Food and Drug Administration**

**Before the**

**Subcommittee on Criminal Justice, Drug Policy, and Human Resources**
**Committee on Government Reform**
**House of Representatives**

# "Pharmaceutical Supply Chain Security"

**July 11, 2006**

Release Only Upon Delivery

**INTRODUCTION**

Good morning, Chairman Souder and Members of the Subcommittee, I am Randall W. Lutter, Ph.D., Associate Commissioner for Policy and Planning, at the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to testify about FDA's efforts regarding counterfeit prescription drugs.

While the United States drug supply is among the safest in the world, we believe there are increasingly sophisticated threats from drug counterfeiters. Organizations and individuals who peddle fake medicines put unsuspecting patients at risk, by exposing them to unknown contaminants and denying them medicines known to be safe and effective at treating their medical ailments. Counterfeit drug products and illicit drug diversion are major concerns to FDA. Our focus is to protect the public health and I will discuss measures FDA has taken and continues to take to fight phony medicines.

I serve as co-chair of FDA's Counterfeit Drug Task Force. The Task Force was established in 2003 and consists of senior FDA officials. Our mission is to develop recommendations for steps FDA, other government agencies, and industry could take to minimize the risks to the public from counterfeit drugs getting into the U.S. drug distribution system. Today, I would like to highlight some of the work of the Task Force and some of the recommendations made in the Task Force's 2006 Report.

**Definition of Counterfeit Drugs under the Federal Food, Drug, and Cosmetic (FD&C) Act**

U.S. law defines counterfeit drugs as those sold under a product name without proper authorization, where the identity of the source of the drug is knowingly and intentionally mislabeled in a way that suggests that it is the authentic approved product. This definition can apply to brand name products, generic products, or the bulk ingredients used to make the drug product. Counterfeit drugs under this definition may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with packaging that falsely suggests the drug was manufactured by the FDA-approved manufacturer.

This definition focuses on fraud and deception toward the consumer (i.e. when persons falsely believe they are receiving the genuine FDA-approved product) and generally does not include products that are marketed as being similar to or a foreign version of an FDA-approved drug. Those types of products are also illegal, but referred to as "unapproved new drugs," not counterfeit drugs.

**Combating Prescription Drug Counterfeiters**

Although our experience (and that of our stakeholders) tells us that the number of counterfeit drug products entering the U.S drug supply chain remains low, the Agency has witnessed an increase in counterfeiting activities and a greater capacity to introduce counterfeit drugs into legitimate drug distribution channels. The number of newly initiated counterfeit drug cases has risen from just a few years ago. In fiscal year (FY) 2004, FDA's Office of Criminal

Investigations (OCI) initiated 58 counterfeit drug cases, a significant increase from the 30 cases initiated in FY 2003 and from an average of less than 10 cases per year in the 4 years before 2001. Although the number of counterfeit drug cases opened by OCI in FY 2005 dropped to 32, preliminary numbers of such cases opened at this point in FY 2006 suggests that there will be an increase in line with the number of cases opened in FY 2004. Fortunately, most of the counterfeit drugs at issue did not reach consumers because we focused our resources and proactively developed investigations. We believe that this proactive strategy enabled us to identify and interdict counterfeit drug products before they entered retail distribution.

Let me stress that the number of opened OCI counterfeit drug investigations should not be relied upon as a measure of the volume of counterfeit drugs, or as an indication of the prevalence of drug counterfeiting, in the U.S. These are simply numbers of newly opened cases: a single case may involve several types of counterfeit drugs being offered for sale, and multiple doses of each of these drugs.

Nearly 4 billion prescriptions were filled last year. That means a very large volume of drugs is moving through the supply chain. The sophistication and precision of some counterfeit copies of legitimate drugs make a reliable estimate of the number of counterfeits impossible. However, we believe that existing regulations and the vigilance by most supply chain stakeholders keep the prevalence of drug counterfeiting in the U.S. very low. An appendix to this statement contains recent examples of significant OCI counterfeit drug and drug diversion

cases. Many of these cases were successful because of our joint efforts with other enforcement agencies such as U.S. Immigration and Customs Enforcement (ICE).

**FDA's Counterfeit Drug Initiative**

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs. This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the product and packaging;
- Secure the movement of drugs through the supply chain;
- Secure business transactions;
- Ensure appropriate regulatory oversight and enforcement;
- Increase penalties;
- Heighten vigilance and awareness; and
- International cooperation.

To implement these measures, the 2004 Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- Radio Frequency Identification (RFID) is a promising technology as a means to achieve electronic pedigree (e-pedigree);

- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the Prescription Drug Marketing Act (PDMA) should be delayed until December 1, 2006, in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report, which assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID technology during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting a 2007 goal of widespread use of e-pedigree across the drug supply chain;
- If it appeared that the 2007 goal would not be met, FDA planned to consider options for implementing the provisions of the PDMA rulemaking that are the subject of the stay; and
- FDA would identify what we could do to address obstacles to the widespread adoption of RFID.

As the Task Force continued to monitor the adoption and implementation of e-pedigree and electronic track and trace technology, we recognized that adoption across the U.S. drug supply chain was slower than originally anticipated. To determine whether widespread use of e-pedigree by 2007 was still feasible, and to solicit public comment on the implementation of certain PDMA-related regulations, we held a public meeting on February 8 and 9, 2006. Our objectives for the meeting were to:

- Identify incentives for, as well as any obstacles to, the widespread adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit public comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of development of electronic track and trace and e-pedigree technology solutions.

In June of this year, the Task Force issued its most recent report, based on an extensive fact-finding effort. The report contained recommendations that were fully endorsed by the Acting Commissioner and this testimony provides some highlights from the report. (The FDA Counterfeit Drug Task Force Report: 2006 Update is included in the Appendix to this testimony.)

**Prescription Drug Marketing Act (PDMA)**

The PDMA, as modified by the Prescription Drug Amendments of 1992 (PDA), amended the FD&C Act to, among other things, establish requirements related to the wholesale distribution

of prescription drugs in interstate commerce. Section 503(e)(1)(A) of the FD&C Act requires that

> "...each person who is engaged in the wholesale distribution of a drug...who is not the manufacturer or authorized distributor of record of such drug shall... provide to the person who receives the drug a statement...identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)"

In December 1999, FDA published final regulations (Title 21, *Code of Federal Regulations* (CFR) part 203) related to the PDMA that were to take effect in December of 2000. After publication of these regulations, FDA received numerous communications from stakeholders objecting to the requirements in 21 CFR §§203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" (ADR), set forth requirements regarding an identifying statement (commonly referred to as a "pedigree"), and define the fields of information that must be included in the pedigree.

FDA delayed the effective date for those provisions several times until 2004 because of issues raised by stakeholders. They contended that some secondary wholesalers may not receive pedigree information from their suppliers who meet the PDMA's definition of "authorized distributor" because the PDMA does not require ADRs to provide pedigrees. They expressed concern that their inability to meet the regulations' requirements would frustrate sales and drive them out of business.

In 2004, FDA further delayed the effective date until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would be able to adopt electronic track and trace technology by 2007. When widely adopted, this technology would create a de facto universal e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, a universal e-pedigree could meet the statutory requirements in section 503(e) of the FD&C Act.

FDA is committed to minimizing opportunities for counterfeiters and diverters to infiltrate our nation's drug supply with counterfeit drugs. Our extensive experience with counterfeit and drug diversion cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Based on our recent fact-finding effort, we can no longer justify continuing the stay. Many supply chain stakeholders told FDA that the regulations should go into effect. In addition, some states are moving forward with their own pedigree laws. Allowing the stay to expire will provide clarity in the prescription drug supply chain by distinguishing who is an ADR, and would therefore be exempt from providing a drug pedigree, from non-ADRs who must provide a pedigree.

Although the regulations do not provide for a phased-in approach to pedigree implementation, FDA has issued a draft compliance policy guidance (CPG) for public comment that reflects the risk-based approach that FDA will use to focus its enforcement efforts regarding the pedigree regulations. The focus will be on prescription drug products that are most vulnerable to counterfeiting and diversion or otherwise involved in illegal activity. The CPG

should help law-abiding secondary wholesalers adjust to the regulations by giving them an idea of where and how to focus their initial resources as they come into compliance. FDA is currently receiving comments on the draft CPG and will expeditiously review and analyze them. We expect to issue a final CPG before December 1, 2006, effective for one year.

**Recommendations for Electronic Track and Trace Technology**

FDA stated, in the 2006 Task Force Report, that although significant progress has been made to set the stage for widespread use of e-pedigree, this goal, unfortunately, will not be met by 2007. FDA is optimistic that the considerable momentum and interest in widespread implementation of e-pedigree will continue and remains committed to working with stakeholders to expeditiously make this happen.

The 2006 Task Force Report also states that FDA continues to believe that RFID is the most promising technology for implementing electronic track and trace in the prescription drug supply chain and that stakeholders should move quickly to implement this technology. FDA recognizes that implementing an RFID-enabled drug supply chain is challenging and urges manufacturers to take a risk-based approach to implementation by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of counterfeiting, and prior history of counterfeiting or diversion, among other things. Stakeholders urged FDA not to mandate RFID in order to give the private sector time to continue with developing standards and build the appropriate and necessary infrastructure. We listened to their concerns and did not require RFID use at this time.

The 2006 Report also considered several technical issues related to adoption of electronic track and trace technology that were perceived as obstacles to implementation and are in need of resolution. These include:

- Mass serialization and unique identification of each drug package;
- Universal pedigree with national uniform information; and
- Privacy issues and the need for consumer education about RFID and the labeling of RFID-tagged drug products in order to help prevent unauthorized disclosure of personal information.

**CONCLUSION**

FDA's vision of a safe and secure prescription drug supply chain is based on transparency and accountability by all persons who handle the prescription drug throughout the supply chain. With the implementation of the pedigree regulations in December 2006, FDA expects that supply chain stakeholders will move quickly to adopt electronic track and trace technology, implementing RFID or an alternative track and trace technology in a phased-in approach. Although there are important issues that still need resolution, these issues should not hinder the forward progress and momentum toward widespread adoption. In the meantime, FDA believes that public health would be better protected if all stakeholders work cooperatively to enable all distributors to pass pedigrees.

FDA will do its part in effectively enforcing the law, in conjunction with other Federal, state, and local entities, to protect Americans from criminals who attempt to undermine the public

health by introducing counterfeit and diverted prescription drugs into the U.S. drug supply. At the same time, stakeholders must remain vigilant in their responsibility to provide safe and effective drug products to U.S. patients.

I would like to thank the Subcommittee for this opportunity to testify today on this important issue. I would be pleased to respond to any questions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

**MEMORANDUM**

DATE: June 8, 2006

TO: Randall Lutter, Ph.D.
Associate Commissioner for Policy and Planning

Margaret Glavin
Associate Commissioner for Regulatory Affairs

FROM: Andrew vonEschenbach, MD
Acting Commissioner of Food and Drugs

Thank you for submitting to me the Counterfeit Drug Task Force Report – 2006 Update. I strongly concur that increasing the safety and security of the nation's drug supply and protecting it from the increasing sophisticated threat of counterfeit drugs is critically important. I commend you and the rest of the Counterfeit Drug Task Force on your efforts in developing this report and its recommendations to further this goal. I appreciate the fact-finding efforts that the Task Force undertook, such as holding the February 2006 public workshop and soliciting public comment, to understand the issues and provide me with informed recommendations.

I endorse the report and its recommendations. This includes the recommendation not to further extend the stay and to issue a compliance policy guide (CPG) that discusses FDA's enforcement focus regarding pedigree requirements. Please move forward with these recommendations, pursuant to FDA's good guidance practice (GGP) process (21 CFR § 10.115), as appropriate.

Andrew C. von Eschenbach, M.D.

# FDA COUNTERFEIT DRUG TASK FORCE REPORT: 2006 UPDATE

## I. INTRODUCTION

This report is based on the work of the Food and Drug Administration's (FDA or Agency) Counterfeit Drug Task Force.[1] It is the third report issued by the Agency since 2004 to address FDA's and the private sector's response to the emerging threat of counterfeit drugs entering the U.S. drug supply. This report contains recommendations to FDA's Acting Commissioner regarding actions that the public and private sector can take to further speed the adoption of electronic track and trace technology and for the use of pedigrees in general, to increase the safety and security of the U.S. drug supply.

After discussing the background and public comment on the issues addressed in this report, we discuss our recommendations or conclusions regarding:

- The expiration of the stay of 21 CFR §§ 203.3(u) and 203.50;
- The extent to which electronic track and trace technology is being used across the supply chain for electronic pedigrees and the use of radio-frequency identification (RFID) for drug products in the drug supply chain; and
- Technical issues related to the implementation of electronic track and trace technology, such as mass serialization, universal and uniform pedigrees, data management, and privacy issues.

## II. BACKGROUND

### A. The Counterfeit Problem

Counterfeit prescription drugs are illegal, generally unsafe, and pose a serious threat to the public health. Many are visually indistinguishable from authentic drugs. As we stated in our first Counterfeit Drug Task Force report in 2004 (2004 Report),[2] we believe that counterfeiting is quite rare within the U.S. drug distribution system because of the extensive scheme of federal and state regulatory oversight and the steps taken by drug manufacturers, distributors, and pharmacies, to prevent counterfeit drugs from entering the system. However, we are concerned that the U.S. drug supply is increasingly vulnerable to a variety of increasingly sophisticated threats. We have witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.

### B. The 2004 Counterfeit Drug Task Force Report & 2005 Update

In 2004, the Task Force issued a report outlining a framework for public and private sector actions that could further protect Americans from counterfeit drugs, including implementation of new track and trace technologies to meet and surpass goals of the Prescription Drug Marketing Act (PDMA).[3] This framework called for a multi-layer approach to address the problem and included the following measures:

- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

In order to implement these measures, the Task Force Report stated, among other things, that:

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007; and
- The effective date of certain regulations related to the implementation of the PDMA should be delayed until December 1, 2006 in order to give stakeholders in the drug supply chain time to focus on implementing widespread use of e-pedigree.

In 2005, the Task Force issued an annual update report (2005 Report)[4]. The 2005 Report assessed FDA's and industry's progress toward implementing the 2004 recommendations. In the 2005 Report, the Task Force found, among other things, that:

- Stakeholders had made significant progress in developing and implementing RFID during the previous year;
- FDA was encouraged by the progress stakeholders, standard-setting bodies, and software and hardware companies had made toward implementing an e-pedigree for drug products and that we were optimistic that progress would continue in an expeditious manner toward meeting FDA's 2007 goal of widespread use of e-pedigree across the drug supply chain;

- If it appeared that the 2007 goal would not be met, we planned to consider options for implementing the provisions of the PDMA rulemaking that are the subject of the stay; and
- FDA would identify what we could do to address obstacles to the widespread adoption of RFID.

**C. 2006 Fact-finding Efforts: Public Workshop, Vendor Display, and Docket**

As the Task Force continued to monitor the adoption and implementation of e-pedigree and electronic track and trace technology, we recognized that adoption across the U.S. drug supply chain was slower than originally anticipated. To determine whether widespread use of e-pedigree by 2007 was still feasible, and to solicit comment on the implementation of certain PDMA-related regulations, we held a public meeting on February 8 and 9, 2006.[5] Our objectives for the meeting were to:

- Identify incentives for, as well as any obstacles to, the widespread adoption of RFID across the U.S. drug supply chain and possible solutions to those obstacles;
- Solicit comment on the implementation of the pedigree requirements of the PDMA and the use of an e-pedigree; and
- Learn the state of development of electronic track and trace and e-pedigree technology solutions.

Over 400 people attended the public meeting. Forty-six presentations were made and 27 vendors participated in the vendor display.

Members of the drug supply chain, the technology sector, special interest groups, academia, health professionals, and consumers also filed sixty comments to the public docket that we opened as part of the public workshop.

In addition, we have been attending conferences, meeting with stakeholders, tracking the status of pilot programs, monitoring changes in and use of technologies, participating in standards development, and closely following other influences to remain up-to-date on the relevant issues.

This report is based primarily on information gathered from these fact-finding efforts. It contains our views on outstanding issues related to e-pedigree and RFID implementation, as well as recommendations for additional public and private measures to support our continuing efforts to further secure our nation's drug supply.

## III. WHAT IS NEXT FOR PDMA IMPLEMENTATION?

**What should FDA do regarding the stay of 21 CFR §§ 203.3(u) and 203.50?**

Issue/Background

The PDMA as modified by the Prescription Drug Amendments of 1992 (PDA) amended the Food, Drug, and Cosmetic Act (the Act) to, among other things, establish requirements related to the wholesale distribution of prescription drugs. Section 503(e)(1)(A) of the Act requires that

> "...each person who is engaged in the wholesale distribution of a drug***who is not the manufacturer or authorized distributor of record of such drug *** provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction.)"

PDMA defines an authorized distributor of record as a wholesaler that has an "ongoing relationship" with the manufacturer to distribute the drug. However it does not define "ongoing relationship."

In December 1999, the Agency published final regulations (1999 final rule) (21 CFR part 203) related to the PDMA[6] that were to take effect on December 4, 2000. After publication of the final rule, the Agency received communications from industry, industry trade associations, and members of Congress objecting to the requirements in 21 CFR §§ 203.3(u) and 203.50. These provisions define the phrase "ongoing relationship" as used in the definition of "authorized distributor of record" (ADR), set forth requirements regarding an identifying statement (commonly referred to as a "pedigree"), and define the fields of information that must be included in the pedigree. Those objecting to the regulations explained that some secondary wholesalers may not receive pedigree information from their suppliers who meet the PDMA's definition of "authorized distributor" because the PDMA does not require authorized distributors to provide pedigree information. Without this information, they explained, secondary wholesalers would not be able to sell the drugs because they would be unable to pass a pedigree that met all the requirements of 203.50. Many secondary wholesalers are small businesses and expressed concern that their inability to meet the regulations' requirements would frustrate sales and drive them out of business.

Based on the concerns raised, the Agency delayed the effective date for those provisions until October 1, 2001[7] in order to reopen the comment period for the regulations and receive additional comments. In addition, the House Committee on Appropriations (the Committee) requested that the Agency review the potential impact on the secondary wholesale pharmaceutical industry and prepare a report to the Committee summarizing the comments and issues raised and the Agency's plans to address these concerns. The Agency's report, which

was submitted to Congress in June 2001 (2001 PDMA Report to Congress), concluded that we could address some of the concerns raised by the secondary wholesale industry through regulatory changes, but that some of the changes requested by the secondary wholesale industry would require statutory change.[8] Since submitting the report to Congress, FDA has continued to delay the effective date of these provisions.

In February 2004,[9] FDA again delayed the effective date of the particular provisions until December 1, 2006, because we were informed by stakeholders in the U.S. drug supply chain that industry would adopt electronic track and trace technology by 2007. When widely adopted, this technology could create a de facto e-pedigree that would document the movement of the drug from the place of manufacture through the U.S. drug supply chain to the final dispenser. If properly implemented, e-pedigree could meet the statutory requirements in section 503(e) of the Act.

In our 2006 fact-finding effort, we sought comment on whether to continue the delayed effective date, let the regulations go into effect, amend the 1999 final rule, or take other steps.

What We Heard

Most of the comments[10] to our February 2006 notice advised FDA to implement the regulations and let the stay expire. Some said the regulations should be implemented as currently written, without amendment. Others suggested amending the final rule to either 1) exempt the passing of pedigree along primary supply chain routes or the "normal chain of distribution," or 2) phase-in implementation, starting with requiring pedigrees for those drugs that are susceptible to counterfeiting and diversion, or 3) require a pedigree for "one forward-one back" in the distribution chain (as opposed to a pedigree that documents all prior sales transactions back to the manufacturer). A couple of comments suggested that we extend the stay in order to give industry more time to continue moving toward adoption of electronic track and trace technology and e-pedigree. A few wanted the stay to be extended in order to give time to amend the regulations. The amount of time requested for extending the stay varied from 5 years to indefinitely. We also received one citizen petition from a secondary wholesalers' trade association requesting that the stay be extended.

Some comments suggested that FDA work with Congress to eliminate the provision exempting the authorized distributor of record from having to pass a pedigree. They claimed that it was too confusing to recognize when a pedigree should or should not be passed.

Several comments asserted that implementation of the PDMA regulations would speed the development of new, less expensive ways to provide pedigree.

Discussion

We carefully considered several options and recommend that FDA no longer delay the effective date of §§203.3(u) and 203.50 past December 1, 2006. Regulations defining "ongoing relationship" and "authorized distributor of record" are scheduled to go into effect thereafter. In our 2006 fact-finding efforts, we gave stakeholders and the public ample opportunity to provide their input, but we did not hear the same arguments that we heard on previous occasions regarding why we should further extend the stay. Rather, this time, an overwhelming majority of the comments favored allowing the stay to expire.

The PDMA was signed into law in 1988. We believe that FDA can no longer justify delaying implementation of these regulations. In its 2001 PDMA Report to Congress, FDA shared the concerns that were raised regarding implementation of the regulations. By recommending implementation of the stayed provisions, we are supporting the law that Congress passed and has since retained. Furthermore, our extensive experience with counterfeit and diversion drug cases reveals that the secondary wholesale market is where much of the illegal activity occurs. Allowing the stay to expire will provide clarity in the drug supply chain regarding who is and is not an ADR, requiring those secondary wholesalers who may be involved in illegal activity to provide pedigrees. Continuing the stay would perpetuate the current confusion and further allow opportunities for counterfeit and diversionary practices to flourish.

We do not intend to put secondary wholesalers out of business. We continue to be sensitive to the concerns that they raised several years ago, even though we did not hear these concerns during our current fact-finding effort. Therefore, as explained below, we recommend that FDA take an enforcement approach that focuses on products most susceptible to counterfeiting and diversion, which should relieve some of the burden that secondary wholesalers might confront when these regulations go into effect.

Most of the comments we received in this fact-finding effort recommended that the regulations be implemented as is, while others advocated a phased-in approach, whereby the regulations would apply to a limited number of drugs at first. We agree that the regulations should be implemented as is. Many of the recommended changes to the pedigree requirements would require a change in the law. We believe that the regulations as currently written appropriately interpret and implement the PDMA, as Congress intended.

Although the regulations do not provide for a phased-in approach, we propose that FDA publish a Compliance Policy Guidance (CPG) before the stay expires that will contain a list of factors for FDA field personnel to consider in focusing their efforts when carrying out their duties in enforcing the law. We propose that these factors reflect a risk-based approach in which FDA uses its limited resources to focus on drug products that are most vulnerable to counterfeiting

and diversion. We do not propose the creation of a list of drugs that meet the criteria, but instead suggest that the CPG provide examples. However, we recommend that FDA not limit its enforcement to just those drugs that meet the factors. Rather, the factors would merely provide guidance for where our field personnel should target their enforcement efforts. The factors to consider for the enforcement focus may include drugs with a high value in the U.S. market, drugs with prior indicators (such as drugs that were involved in diversion cases or counterfeiting), and drugs that are easily counterfeited.

We believe that this CPG would be considered a Level 1 guidance under FDA's good guidance practice (GGP) regulations. (21 CFR §10.115.) Therefore, we recommend that FDA publish a draft version for public comment, evaluate the comments, and then publish a final guidance by December 2006.

We recognize that complying with the stayed regulations may require changes in business practices. Compliance may also require implementation of additional information technology systems to generate a pedigree. Each of these processes may take time to achieve. However, we note that, although the regulations at issue have been stayed since 1999, the fundamental statutory requirement to pass a pedigree has been in effect since PDMA was enacted. The regulations primarily serve to clarify who is an authorized distributor of record and what information a pedigree must contain. In addition, we believe that this report and the CPG we advocate herein will focus public attention on this issue such that any wholesalers who thought that they were not subject to the pedigree requirement will have adequate time to take appropriate steps to comply with the regulations.

Furthermore, many States have moved forward with their own pedigree requirements, which often contain requirements in addition to those in the PDMA. We are aware that stakeholders are preparing to meet these State requirements, both electronic (to meet California law) or otherwise. Consequently, they should be that much closer to meeting the federal PDMA requirements as well.

***Recommendation:***

- **We recommend that FDA not continue to delay the effective date of §§203.3(u) and 203.50 beyond December 1, 2006.**
- **We recommend that FDA issue a draft Compliance Policy Guide for public comment that would focus FDA's pedigree-related enforcement efforts on those drugs most vulnerable to counterfeiting and diversion.**

## IV. WHAT IS THE STATUS OF ELECTRONIC TRACK AND TRACE ACROSS THE DRUG SUPPLY CHAIN?

**A. What is the progress of the use of e-pedigree in the drug supply chain?**

Issue/Background

In the 2004 Task Force Report, we said that adoption and widespread use of reliable track and trace technology is feasible by 2007. We stated that this would help secure the integrity of the supply chain by providing an accurate drug "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. We particularly advocated for the implementation of electronic track and trace mechanisms and noted that RFID is the most promising technology to meet this need.

In our 2006 fact-finding effort, we sought comment on the progress of e-pedigree implementation in the drug supply chain to determine if the goals outlined in the 2004 Task Force Report would be met.

What We Heard

Several comments described completed and ongoing pilot programs for e-pedigree and their successful deployment of e-pedigree in a real-time production environment. Most pilot programs involved distribution with one manufacturer, one wholesaler, and, in some cases, one pharmacy. Many comments stated that e-pedigree can be achieved using either RFID or barcodes. A number of comments stated that standards for e-pedigree are complete and that interoperable software is available. A few comments from manufacturers of already-serialized products said that they have developed track and trace systems capable of providing an e-pedigree through existing internet technologies.

Most comments agreed that it was necessary to adopt mass serialization with unique identifiers on each package as an important step to facilitate e-pedigree, while some comments stated that it is not needed. A majority of the comments stated that although widespread use of e-pedigree is not far off, it is hard to predict when that might happen or set a new timetable or a new target date. However, many comments suggested that FDA set a specific date by which all products must have an e-pedigree, arguing that without a specific date progress toward adoption will continue to be slow. Some comments recommended that FDA establish realistic phased-in compliance dates for adoption of e-pedigree.

Discussion

In 2004, we were optimistic that widespread implementation of e-pedigree was feasible by 2007 because we were told by many stakeholders in the drug supply chain that this was a realistic goal. Although significant progress has been made to set the stage for widespread use of e-pedigree, unfortunately, this goal most likely will not be met. We will not issue a new forecast or target date for adoption

of e-pedigree because we do not have enough information to do so at this time. Most comments said that it is difficult to predict or designate a target date. We do believe that a timetable with achievable, realistic milestones is crucial to keep e-pedigree implementation on track. Therefore, we recommend that FDA continue to work with members of the drug supply chain to develop such a timetable.

We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps to implement an e-pedigree and States that have championed this cause, such as California. However, it is clear from our recent fact-finding efforts that the voluntary approach that we advocated in the 2004 Task Force Report did not provide industry with enough incentives to meet FDA's deadline. The mere "risk" of the PDMA regulations being implemented was not enough of an incentive. When PDMA was enacted, the state of technology was not as advanced as it is today, and, as a practical matter the industry could pass only paper pedigrees.

We understand the complexity in moving toward an e-pedigree and recognize that a hybrid approach using both paper and electronic pedigrees will be needed during a transition period. We continue to believe that RFID is the most promising technology for electronic track and trace across the drug supply chain. However, we recognize that the goals can also be achieved by using other technologies, such as 2D-barcodes. Based on what we have recently heard, we are optimistic that this hybrid environment of electronic/paper and the use of RFID/bar code is achievable in the very near future. We believe that efforts to ensure that hybrid pedigrees are secure and verifiable should be a priority consideration.

If legislation is considered in Congress related to e-pedigrees, we stand ready to provide technical assistance.

***Recommendation:***

- **We recommend that stakeholders work cooperatively to continue to expeditiously implement widespread use of electronic pedigrees across the drug supply chain.**
- **We recommend that FDA provide technical assistance if legislation related to electronic pedigrees is considered in Congress.**

**B. What is the progress of the use of RFID on drug product packages?**

Issue/Background

We sought comment on the implementation status of RFID, including a description of the obstacles to widespread adoption, an estimate of the timetable, the suggested role of FDA, and the incentives needed to promote adoption.

What We Heard

A majority of the comments agreed that RFID is the most promising technology for track and trace in the drug supply chain. We received many comments describing current obstacles to wider adoption of RFID, including:

- A lack of standards (for e-pedigree fields and format, data systems, international transmission standards, and hardware specifications);
- Privacy concerns;
- Concerns about the ownership of confidential business transaction data;
- Challenges in serializing all products;
- Concerns over the accuracy and speed of electronic devices and systems; and
- A lack of definitive data to determine how RFID will affect sensitive products (e.g., liquids, biologics).

Many comments stated that it is not possible to predict or estimate a timetable for widespread adoption of RFID, or stated that widespread RFID adoption is at least many years away. Some comments estimated that it will take up to 10 years. Many comments suggested that technical issues (e.g., adoption of standards, product/software development) would need to be settled before a more accurate timetable could be estimated. A number of comments suggested a phased-in approach for RFID adoption to provide industry sufficient time to explore all options. One comment from a stakeholder closely involved in the development of RFID technology stated that the FDA timeline for RFID adoption is technically feasible, that is, widespread adoption of RFID is feasible by 2007.

Comments noted that progress toward the full adoption of RFID technology is occurring, but that adoption is moving more slowly than previously anticipated. Several pilot projects have been conducted or are underway to test the feasibility of RFID deployment along the prescription drug supply chain, but data is limited.

Most comments said that FDA should not mandate or require the use of RFID in the drug supply chain. Instead, some comments said that FDA should continue to encourage the use of RFID. Many comments said that FDA should actively participate in, support, and facilitate RFID activities, especially those activities of groups working to establish RFID standards and implementation. In addition, many comments said that FDA should take a lead role in developing a public education program about the use of RFID technology on drug products.

Most comments said that incentives would help in the adoption of RFID across the supply chain. Only one comment said that no incentives are needed. Comments suggested the following incentives:

- Financial/tax incentives;

- Mandating mass serialization on drug products, but allowing industry to determine the most appropriate technology to ensure compliance;
- Statutory changes.

Discussion

We continue to believe that RFID is the most promising technology for implementing electronic track and trace in the drug supply chain and that stakeholders should move quickly to implement this technology. We appreciate the candid views and concerns that were shared with us during this fact-finding effort in identifying obstacles to implementation. Within this report, we have tried to address the issues related to those obstacles that are within FDA's purview.

Although we are encouraged by the efforts of GlaxoSmithKline, Pfizer, and PurduePharma in tagging their products, and the efforts of many other companies and wholesalers in exploring and piloting RFID, we are disappointed with the lack of overall progress across the drug supply chain. In the 2004 Task Force Report, we laid out milestones and goals for RFID implementation based on credible information that stakeholders gave us. Many of these milestones have not been met. The technology vendors uniformly told us that their RFID and e-pedigree solutions and technologies are ready to go, but manufacturers, wholesalers, and retailers are slow to implement them.

We recognize that progress may have been delayed because standards have not yet been established. However, we are encouraged by the progress that industry has made to develop and adopt universal standards. Based on what we heard, those standards are close to completion. Once completed, we would expect to see a rapid growth in the implementation of RFID in the drug supply chain. We look forward to continuing to participate and support this standards development process.

In November 2004, FDA issued a CPG for conducting pilot studies for RFID tagging. In that CPG, FDA excluded biological products as eligible for these pilot studies because we had insufficient information about the impact of radio-frequency (RF) on biologics. To date, we have not received sufficient information to change this policy. Therefore, the CPG continues to remain in effect as written until December 31, 2007. In order to further our understanding of the impact of RF, we have begun our own study to evaluate the potential impact of RFID on drug and biological products. We expect to share the results of this study later this year.

We recognize that implementing an RFID-enabled drug supply chain is challenging. We appreciate the comments advocating a phased-in approach and urge manufacturers to take a risk-based approach to implementation by first tagging the products that are most vulnerable to counterfeiting and diversion, based on factors such as the sales price, volume sold, demand, ease of

counterfeiting, and prior history of counterfeiting or diversion, among other things. If a company's products are not "at risk", then we would suggest the company choose its highest volume/highest sale drug(s) and start piloting. Although RFID deployment does have significant start up costs, based on our discussions and what we heard, most stakeholders agree that there are also significant benefits. Not only does the track and trace capability of RFID provide anti-counterfeiting and supply chain security benefits, but it also offers significant savings in the form of better inventory management, reduction in theft and product loss, improved recall efficiency, and reduced paperwork burdens.

RFID also has tremendous potential benefits for drug products used in public health emergencies, such as a pandemic influenza or a bioterrorist attack. RFID tracking could help in expeditious deployment and redeployment of medical countermeasures in times of crisis. FDA should, therefore, encourage manufacturers of these types of products to explore the use of RFID.

We agree with the comments that FDA should not mandate RFID. Although in 2004, we sought voluntary adoption and more widespread use by 2007, we believe that the private sector momentum is moving and that our input on some of the perceived obstacles may jumpstart further adoption interest and momentum. In the 2004 Task Force Report, we laid out a timetable for mass serialization and RFID implementation, as well as steps for businesses and standard-setting issues. Although the timetable goals were not met, we continue to stand by this approach and are prepared to work with stakeholders who wish to take the lead in developing a new, feasible, yet ambitious, timetable.

***Recommendation:***

- **We recommend that stakeholders continue moving forward in implementing RFID across the drug supply chain.**
- **We recommend that stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.**
- **We recommend that FDA remain committed to facilitating RFID implementation and working with stakeholders, standards organizations, and others.**
- **We recommend that FDA work quickly to complete its RFID Impact Study examining drugs and biologics, and publicly share the results.**
- **We recommend that stakeholders explore the use of RFID for tracking medical countermeasures.**

**V. WHAT TECHNICAL ISSUES RELATED TO ELECTRONIC TRACK AND TRACE NEED RESOLUTION?**

**1. Mass Serialization**

Issue/Background

Mass serialization involves the incorporation of a unique identifier number on each drug package in order to track the individual drug package as it moves through the drug supply chain. We sought comment on mass serialization numbering schemes, including the preferred numbering convention, the merits of incorporating the National Drug Code (NDC) number and its impact on patient privacy, and the timetable for mass serialization across the drug supply chain.

What We Heard

Almost all the comments recommended that industry use a single numbering convention to reduce costs and complexity. One comment noted that multiple numbering schemes could lead to conflicts (e.g., duplicate numbers for the same item) and incompatibility between points in the distribution chain. Several comments suggested that using random numbers for the product identification component of the electronic product code (EPC) could increase security, while concealing proprietary information about the product or manufacturer. However, other comments suggested that the EPC should include the manufacturer ID as part of the code.

Many comments addressed whether or not the NDC should be included in the unique identifier. Many comments were concerned that RFID tags could be surreptitiously read, and if the NDC was included, it could jeopardize the privacy of patients and potentially endanger the drug supply chain. However, pharmacies and their trade groups supported the inclusion of the NDC, arguing that their information systems currently identify products by using the NDC and that they might incur significant costs to change these systems if they used an EPC that did not include the NDC. Some of these comments also noted that the NDC plays an important role in the dispensing process and it would be disruptive to workflow to have to consult another database to link the EPC number to the NDC number. However, a couple of the comments noted that it is not necessary to include the NDC as a component of the unique identifier because, pursuant to FDA regulations (21 CFR §§ 201.2 or 201.25), the NDC is printed on most drug packaging.

Finally, several comments from stakeholders that are closely involved in developing the EPC standards suggested that the numbering convention be sufficiently flexible to accommodate standards-based numbering systems already in use (e.g. NDC for pharmaceuticals, UID for U.S. Department of Defense, EAN.UCC for consumer goods.)

Discussion

We continue to believe that using mass serialization to uniquely identify all drug product packages in the U.S. is a powerful tool in securing the nation's drug

supply. The issues surrounding which numbers should be included in this unique identifier are complex. The NDC number is ubiquitous as an identifier of drug products for inventory, dispensing, and claims adjudication, among other things. However, because it is such a recognized number, an NDC number could compromise patient privacy and supply chain security if it could be read surreptitiously.

We believe that the NDC number is an important product identifier and it should be closely associated with the product. We note that, currently, for most prescription drug product packages, the NDC number is either printed on the packaging or included in a bar code on the package. We do not anticipate this practice to change.

We also recognize that inappropriate access to the NDC number on individual products raises patient privacy and security issues. These competing concerns, however, can be addressed through IT solutions. Therefore, we believe that for drug product packages using RFID or other non-line-of-sight technologies, the unique identifier should either include an encrypted NDC number or provide an accessible link to the NDC number that is readily available to pharmacies to facilitate their needs.

Ideally, there should be one numbering scheme used in the drug supply chain. We recognize that the technology continues to advance and it is difficult to predict what its capabilities will be in the near future.

***Recommendation:***

- **We recommend that the NDC number should continue to be closely associated with the product.**
- **We recommend that for non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy.**

**2. Universal Pedigree and Uniform Pedigree Fields**

Issue/Background

The PDMA limits who is required to pass a pedigree and authorizes FDA to determine what information should be included in the drug pedigree. This information is codified at 21 CFR 203.50. Some States have laws imposing pedigree requirements on members of the drug supply chain not covered under the PDMA. Some States have enacted laws requiring additional information to be included in pedigrees passed with drugs sold in their State. In addition, State requirements differ with respect to the information that must be included in the pedigree. We sought comment on what information pedigrees should contain and how such a uniform standard could be achieved.

What We Heard

Nearly all comments encouraged FDA to implement federal uniform pedigree requirements and standards binding on the drug supply chain and States. Several comments noted the work of stakeholder initiatives, including the Uniform Pedigree Task Force and the EPCglobal e-pedigree standards working group. These stakeholder initiatives suggested data fields that could be captured in a uniform pedigree, including:

- Product Information: drug name, manufacturer, product NDC, dosage form, strength, container size;
- Item Information: lot number and expiration date, quantity of units by lot, product serial number (if serialized);
- Transaction Information: transaction identifier (e.g., PO, invoice) and date, transaction type (e.g., sale, transfer, return), date received;
- Trading Partner Information: business name, address and license of seller, alternate ship-from location of seller, seller contact information for authentication, business name, address and license of recipient, alternate ship-to location of recipient;
- Signatures/Certifications: digital signature of seller, digital signature of recipient.

There was near complete agreement that all wholesalers, not just non-authorized distributors, should be responsible for passing pedigree information. Many of these comments urged FDA to take appropriate steps to require a universal and nationally uniform e-pedigree so that stakeholders do not have to comply with 50 different State pedigree requirements.

Discussion

The PDMA requires a statement/pedigree ("in such form and containing such information as the Secretary may require") to be passed with certain wholesale distributions. The PDMA and FDA's pedigree-related implementing regulations define the information that must be included in a pedigree.

We continue to believe that a universal e-pedigree (i.e., a pedigree passed by all wholesalers, not just those who are not authorized distributors of record) that documents the movement of every prescription drug product from the manufacturer to the dispenser would be an important step in preventing counterfeit drugs from entering the drug supply chain.

We also agree with the comments that a single, national, uniform pedigree would be ideal to help ensure efficient distribution of safe and effective medicines. To be most effective and efficiently communicate chain of custody and other information about the drug product, it would be ideal if all members of the drug

supply chain passed a pedigree that was uniform across all States. Fifty different State pedigrees will no doubt create confusion in the marketplace and could stifle interstate drug trade. For example, the pedigree laws that were enacted in Florida, California, Indiana, and other States contain different requirements.

Under existing law, FDA lacks statutory authority to implement a universal and nationally uniform pedigree. If legislation is considered in this area, we stand ready to provide technical assistance.

***Recommendation:***

- **We recommend that FDA provide technical assistance if legislation in this area is considered in Congress.**

**3. Data Management/Data Security**

Issue/Background

For e-pedigree transmission to be successful throughout the drug supply chain, business partners at each point in the supply chain should be able to share information effectively and efficiently. The choice of data management practices and standards becomes an important one for all stakeholders. One issue that has been raised is whether the data/information should be stored in one central database or if a distributed approach (where each stakeholder's system exchanges information with other systems) should be used.

What We Heard

A majority of the comments advocated the use of a distributed database approach to data management. Many noted that a centralized database would be more costly, slower to implement, a threat to patient privacy, and could disrupt drug distribution if the database was unavailable or compromised for some reason. Comments suggested that secure peer-to-peer transactions would be possible under the distributed model. One comment suggested that data management be controlled centrally via a third party, contractually-managed by FDA.

A few comments suggested specific data security measures, such as pedigree documents having digital signatures to maximize document integrity, authentication, and non-repudiation. Some comments referred to existing data transmission standards used elsewhere, specifically Public Key Infrastructure, Federal Information Processing Standards, and the ISO/ICE standards 17799 or 12207. One comment noted that e-pedigrees could be authenticated electronically, using electronic verification of the digital signature and the signed transaction content for each transaction. One comment promoted the use of biometric log-on methods to improve security.

Discussion

It is vital that specific event information contained in the electronic pedigree be secure. We have no preference as to whether the data is housed in a central database or in a distributed scheme. Based on what we heard, it is our understanding that e-pedigree is technologically feasible with either model and even in a hybrid environment, where some data is stored in a central database while other data is distributed across company servers. We believe it would be most efficient to let the market and technology dictate how to best capture and access the data in e-pedigrees.

We do believe that it is essential that every entity in a drug product's chain of custody has access to the product's pedigree data all the way back to the manufacturer, in order to verify and authenticate the pedigree. It is also important for FDA to have access to the information in matters of suspect illegal activity.

***Recommendation:***

- **We have no preference whether a distributed versus central database is used, as long as every entity in the chain of custody for the product has access to information about that product all the way back to the manufacturer.**

**4. Privacy Issues**

**A. Labeling/Disclosure/Education**

Issue/Background

There is general concern that an unauthorized person might be able to read the information from an RFID tag on a drug without the possessor of the drug knowing it, possibly disclosing personally identifiable information or the name of the drug. We sought comment on whether privacy concerns are warranted and whether it is possible for an unauthorized person to read the information from an RFID tag on a drug once that drug is in the consumer's possession. If so, what type of information could be accessed? We also sought comment on how to make consumers aware that an RFID tag is on the drug package and the type of consumer education that would be needed as the use of RFID in the drug supply chain becomes more prevalent.

What We Heard

The majority of the comments indicated that privacy safeguards are needed. However, some pharmaceutical organizations said that patient privacy issues are

not a major concern because many of the prescriptions filled at pharmacies are not dispensed in the original bottles from the manufacturer; the prescriptions are instead placed in a consumer-size container, which would not have an RFID tag. Some comments cited concern about persons gaining unauthorized access to information about the type of drug being taken as well as personal identifying information. Several comments said that the RFID tag should not contain information that identifies the drug (e.g., NDC number). Instead, these comments suggested that the tag should contain a random serialized number so that anyone reading the tag would see only a meaningless number.

Many comments referred to the importance of consumer notice and choice and the use of fair information practices. Comments noted that notice of the presence of an RFID tag on a drug package should be clear, conspicuous, and accurate. Several comments indicated that one way to address the issue of consumer notice is to use a symbol on the package. There was uncertainty, however, as to where the symbol should be placed.

Some comments pointed out that many concerns about privacy are due to concerns about database security (i.e., once the data is collected from an RFID tag, how secure is the database where it is stored?).

The majority of comments said that consumer education is needed for the successful adoption of RFID across the drug supply chain. Many comments indicated that consumers should be informed of the benefits of RFID (e.g., how RFID can help secure the drug supply chain), as well as the risks associated with the technology (e.g., potential threat to privacy). According to some comments, consumers should also be educated about the options that are available for deactivating or removing the RFID tag. Most comments said that FDA, as well as experts in academia, industry, and patient and consumer groups, should be involved in developing education programs.

Discussion

Privacy issues are a real concern for consumers and FDA. These concerns will continue unless there is appropriate disclosure of the presence of an RFID tag on containers given to patients and sufficient education about the application, true risks, benefits, and vulnerabilities associated with RFID tags on drug products. This is no easy task.

Although we support the use of a statement or symbol to disclose the presence of an RFID tag on a drug product package, it is important that manufacturers work with FDA to develop an appropriate message or symbol. Most statements made on the labeling of prescription drug products are regulated by FDA and subject to agency pre-approval. We, therefore, recommend that manufacturers should work with FDA before choosing a statement or symbol to add to their product labeling.

We also are willing to work with stakeholders to develop a uniform statement or symbol that can be used to signal the presence of an RFID tag on a drug product package to use in educational campaigns. Such campaigns would help consumers to readily identify and understand the meaning of the statement or symbol.

We do not propose to issue guidance at this time regarding statements or symbols on drug product labeling to indicate the presence of an RFID tag.

Consumer education is necessary. Potential messages could include educating consumers about RFID, the benefits of its use for patient safety, the privacy risks, possible risks from RF emission, and deactivation and removal of the tag. We do not currently have the resources to lead educational efforts. However, we will work with manufacturers and other stakeholders in their efforts.

***Recommendation:***

- **We recommend that FDA work with manufacturers and other stakeholders in their efforts to develop appropriate messages, symbols, or statements for labeling of drug products and packaging that contains an RFID tag.**
- **We recommend that FDA work with private and public sector organizations in their efforts to educate consumers about RFID.**

**B. "Turning Off" the RFID Tag**

Issue/Background

Some people have suggested that the RFID tag should be "turned off" or deactivated before it leaves the pharmacy, or that patients should be given the choice of whether it is "turned off". We sought comment on the advantages, disadvantages, and feasibility of deactivating the tag.

What We Heard

Many comments indicated that deactivating or removing the RFID tag at the point of purchase (i.e., the pharmacy) would effectively address privacy concerns. However, some comments pointed out that while deactivating or removing the tag would address privacy concerns, it may also prevent post-sale benefits (e.g., recalls) which would have been possible had the tag remained active/in place.

Some pharmacy groups said that the tag should be deactivated prior to arrival at the pharmacy retailer to ensure that no patient is inadvertently sent home with an active tag. One comment said that in practice, deactivating the tag at the point of sale is not feasible because it would place too much responsibility on pharmacists and may re-expose the drug to unknown radio-frequency effects.

Some comments indicated that FDA should provide guidelines to ensure privacy protections through RFID tag deactivation or removal.

Many comments suggested various deactivation methods. Some of the suggested options were: kill function (total or partial), blocker chips, encryption, read protection, decommissioning with individual tag password, tag destruction, placing RFID tagged objects in a foil lined bag (which would prevent unwanted reads), and database controls. There was no consensus on the best deactivation method. However, a standards organization commented that it is evaluating tag deactivation, taking into consideration the consumer and industry benefits of post-sale uses of RFID tags. The point in the supply chain where RFID tags should/could be deactivated is also being evaluated.

Discussion

There are benefits to both keeping the RFID tag active after sale and deactivating it before dispensing the product. We believe that an active tag can provide valuable information if the drug product finds its way back into the drug supply chain. FDA has found counterfeit and diverted drugs in the drug distribution system when drug wholesalers, third-party return entities, or manufacturers return drugs for credit and/or destruction. Those products with active tags would be easier to identify and track through the supply chain. That said, we respect the privacy concerns, however, and do not believe that it is necessary for an active tag to go to the patient.

It is unclear whether technological methods to deactivate the tag in the normal course of business are mature enough for use in the marketplace at this time. We believe that this issue warrants further discussion among stakeholders, technology experts, and consumers, about the viable options and we are not prepared to make a recommendation at this time.

***Recommendation:***

- **We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.**

## V. CONCLUSION

FDA's vision of a safe and secure drug supply chain is premised on transparency and accountability by all persons who handle the prescription drug, starting with the manufacturer and ending with the pharmacist who hands the drug over to the patient. Drug supply chain efforts that capitalize on advances in electronic track and trace technology to create a secure electronic pedigree further this vision.

With the implementation of the PDMA regulations in December 2006, we expect that supply chain stakeholders will move quickly to adopt electronic track and

trace technology, implementing RFID in a phased-in approach. We recognize that there are important issues that still need resolution, such as privacy concerns and uniform and universal pedigrees that might benefit from further discussion by stakeholders or Congress. However, these issues should not hinder the forward progress and momentum toward widespread adoption that we have witnessed and expect to continue. Companies should continue to tag drug products, build infrastructure across the supply chain for using an e-pedigree, and remain vigilant in their responsibility to provide a safe and effective drug product to the patient.

---

[1] The Task Force consists of senior staff from the Office of the Commissioner (Office of Policy and Planning, Office of the Chief Counsel), Office of Regulatory Affairs, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

[2] The FDA Counterfeit Drug Task Force recommendations are detailed in its report, entitled, "*Combating Counterfeit Drugs – A Report of the Food and Drug Administration*," February 18, 2004 (2004 Counterfeit Drug Report) (http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html).

[3] PDMA (Public Law 100-293) was enacted on April 22, 1988, and was modified by the Prescription Drug Amendments (PDA) (Public Law 102-353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 333, 353, and 381) to, among other things, establish requirements related to the wholesale distribution of prescription drug products.

[4] *Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update*, May 18, 2005 (http://www.fda.gov/oc/initiatives/counterfeit/update2005.html).

[5] The workshop agenda, speakers' presentations, and meeting transcript are available at www.fda.gov/rfidmeeting.html .

[6] 64 FR 67720.

[7] 65 FR 25639.

[8] See http://www.fda.gov/oc/pdma/report2001/

[9] 69 FR 8105.

[10] In this report, the term "comments" includes comments that we heard at the public meeting and written comments submitted to the docket.

Mr. SOUDER. Thank you.
Mr. Kevin—is it Delli-Colli?
Mr. DELLI-COLLI. Yes, thank you.
Mr. SOUDER. He is Deputy Assistant Director for Financial and Trade Investigations at ICE. We welcome you back to our committee.

**STATEMENT OF KEVIN DELLI-COLLI**

Mr. DELLI-COLLI. Good afternoon, Chairman Souder and distinguished members of this subcommittee. My name is Kevin Delli-Colli, and I am the Deputy Assistant Director for Financial and Trade Investigations at U.S. Immigration and Customs Enforcement [ICE].

I am pleased to appear before you today to speak about ICE's role in combating the trafficking of counterfeit pharmaceuticals. I have a statement which I will submit for the record and will make a brief oral statement.

In January 2004, ICE and FDA in San Diego began a multi-agency investigation targeting various Web sites, Internet payment networks and pharmaceutical supply chains. The targets utilized more than 650 affiliated Web sites to distribute more than $25 million in counterfeit or unapproved pharmaceuticals within a 3-year period.

The distribution network extended throughout all of North America, and the source country, India, was disguised by trans-shipping the product through other countries. To date, this investigation has resulted in 20 indictments, 18 convictions and the seizure of $1.4 million. The primary violator was sentenced in January 2005 to 51 months imprisonment. Prosecution of other defendants is ongoing. This case highlights many of the challenges confronting U.S. law enforcement in combating the trafficking of counterfeit pharmaceuticals.

As the largest investigative arm of the Department of Homeland Security, ICE plays a leading role in targeting criminal organizations responsible for producing, smuggling and distributing counterfeit products, including counterfeit pharmaceuticals. ICE investigations focus not only on keeping these products from reaching U.S. Consumers, but also on dismantling the criminal organizations responsible for this activity.

ICE smuggling investigations have shown that the Internet has become the primary tool used by organizations engaged in the trafficking of counterfeit pharmaceuticals, whether for advertisement, direct sales or as a communication tool. Individuals who previously would have purchased controlled or prescription pharmaceuticals through an underground supplier now use the Internet to locate a source for the drugs, place orders, arrange shipments, and make payments all from the comfort of their own home. Thus, traffickers have been able to create an illicit unregulated supply chain which is filled with counterfeit, adulterated, misbranded and unsafe drugs that are distributed directly to consumers who in most instances are drug abusers.

The problem is global. China and India are the most prolific source countries; however, Mexico, Thailand and Brazil are also

sources of these drugs. Other countries host Web service, conduct payment processing or act as trans-shipment points.

ICE addresses this threat in several ways. ICE is a cadre of dedicated and trained special agents assigned to domestic field offices who specialize in investigating counterfeit violations. ICE special agents are also deployed to 56 overseas attache offices, making it possible for ICE to effectively conduct global investigations. ICE agents in the field and overseas work closely with the ICE Crime Center to combat pharmaceutical violations over the Internet. ICE also hosts a National Intellectual Property Rights Coordination Center, which serves as the primary point of contact for law enforcement referrals and conducts industry outreach.

Another way in which ICE combats pharmaceutical smuggling is through targeted operations such as Operation Apothecary. Operation Apothecary concentrates its efforts at international mail facilities and express courier hubs to examine and identify packages containing falsely declared or undeclared pharmaceuticals. ICE, FDA and other Federal law enforcement agencies use the information obtained from these examinations to target foreign sources, domestic organizations and recipients engaged in smuggling and distributing commercial quantities of illicit pharmaceuticals.

Since 2003, ICE has initiated 178 criminal investigations targeting pharmaceutical smuggling. To date, these investigations have led to 86 arrests. Millions of dosage units of counterfeit, adulterated, misbranded and unapproved pharmaceuticals have been seized, and where appropriate, assets attributed to the illegal proceeds have also been seized and forfeited.

To combat the supply side, ICE has actively engaged the Chinese Ministry of Public Security to conduct investigations of mutual interest. This dialog led to the first two joint U.S.-China enforcement actions ever to take place in China. One of these investigations began in February 2005 when the ICE attache in Beijing received information that Richard Cowley of Shelton, WA, was linked to groups of individuals involved in the Internet sale of pharmaceuticals in the United States and Europe. This investigation led to the initiation of Operation Ocean Crossing. ICE special agents acting undercover met with Cowley and learned the identity of his supplier in China. The information from this investigation was shared with Chinese authorities, who then took action against the largest counterfeit pharmaceutical operation in China. Twelve Chinese nationals were arrested, and three illicit pharmaceutical facilities were shut down during joint enforcement actions which took place in December 2005. Cowley was arrested in the United States. He has since pled guilty and is currently awaiting sentencing.

This case is an excellent example of the value of cooperation and information sharing in combating transnational pharmaceutical trafficking, and ICE believes that this need for cooperation will continue to produce significant results.

ICE will continue to aggressively apply our authorities in combating the transnational organizations that traffic in counterfeit pharmaceuticals.

This concludes my remarks, and I would be pleased to answer your questions. Thank you.

[The prepared statement of Mr. Delli-Colli follows:]

# U.S. Immigration and Customs Enforcement

**STATEMENT**

**OF**

**KEVIN DELLI-COLLI**

**DEPUTY ASSISTANT DIRECTOR**
**FINANCIAL & TRADE INVESTIGATIONS DIVISION**

**OFFICE OF INVESTIGATIONS**

**U.S. IMMIGRATION AND CUSTOMS ENFORCEMENT**
**DEPARTMENT OF HOMELAND SECURITY**

**BEFORE THE**

**SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY**
**AND HUMAN RESOURCES**

**REGARDING**

**"PHARMACEUTICAL SUPPLY CHAIN SECURITY"**

**TUESDAY, JULY 11, 2006, 10:00 AM**
**WASHINGTON, D.C.**

**2154 RAYBURN HOUSE OFFICE BULDING**

**INTRODUCTION**

Good afternoon Chairman Souder, Ranking Member Cummings and distinguished members of this Subcommittee. My name is Kevin Delli-Colli and I am the Deputy Assistant Director for Financial and Trade Investigations at U.S. Immigration and Customs Enforcement (ICE). I am pleased to appear before you today to speak about the ICE role in investigating individuals and groups involved in the trafficking of counterfeit pharmaceuticals. I will submit a statement for the record, and will make a brief oral statement.

In January 2004, ICE in San Diego initiated a multi-agency investigation that incorporated assets from ICE, the Food and Drug Administration (FDA), U.S. Postal Inspection Service, Internal Revenue Service and Federal Bureau of Investigation (FBI), and which targeted various websites, Internet payment networks and pharmaceutical supply chains. The targets of this investigation used more than 650 affiliated websites to distribute more than $25 million in counterfeit or unapproved pharmaceuticals within a three-year period. The distribution network extended throughout all of North America and the source country, India, was disguised by transshipping the product through other countries. To date, this investigation has resulted in 20 indictments, 18 convictions, and the seizure of $1.4 million. Mark Kolowich, the primary violator, was sentenced in January 2005 to 51 months imprisonment. Prosecution of other defendants is ongoing. This case highlights many of the challenges confronting U.S. law enforcement in combating the trafficking of counterfeit pharmaceuticals.

**THE ICE MISSION**

As the largest investigative arm of the Department of Homeland Security, ICE plays a leading role in targeting the criminal organizations responsible for producing, smuggling, and distributing counterfeit products, including counterfeit pharmaceuticals. ICE investigations focus not only on keeping these products from reaching U.S. consumers, but also on dismantling the criminal organizations that initiate, support and sustain this activity.

There are powerful new tools in the ICE arsenal of border security authorities, which were included in the recently passed reauthorization of the USA PATRIOT Act. The potential sentence for a violation of 18 USC 545 – Smuggling into the United States, was increased from five years to twenty years. That legislation also added, for the first time, an entirely new criminal charge for smuggling from the United States.

By providing ICE with the additional tools necessary to more effectively investigate and combat smuggling and other violations, Congress has simultaneously strengthened ICE's ability to combat violent criminal and terrorist organizations. The special agents who work these important economic, border, homeland and national security cases thank the Congress for this enhancement in 18 U.S.C. 545 and for its continuing strong support of ICE and our important mission.

**PHARMACEUTICALS INVESTIGATIONS and ENFORCEMENT**

ICE smuggling investigations have shown that the Internet has become the primary tool used by organizations engaged in the trafficking of counterfeit pharmaceuticals, whether for advertisement, direct sales or communication. Individuals who previously would have purchased controlled or prescription pharmaceuticals through an underground supplier now use the Internet to locate a source for these drugs, place orders, arrange shipments and make payments.

To date, ICE investigations have not revealed any instances in which smuggled, counterfeit pharmaceuticals were destined for the legitimate U.S. supply chain; rather, trafficking organizations have created an illicit, unregulated supply chain that is filled with counterfeit, adulterated, misbranded and unsafe drugs which are distributed directly to consumers, who in most instances are drug abusers. China and India have been the most prolific source countries for a variety of counterfeit pharmaceuticals, although Mexico, Thailand, and Brazil are also source countries. Other countries serve as transshipment points, locations for web servers, channels for payment processors, and sources for obtaining active primary ingredients.

ICE addresses the threat posed by counterfeit pharmaceuticals in several ways. ICE has a cadre of dedicated and trained special agents assigned to the 26 ICE Special Agent in Charge offices across the nation, who specialize in investigating counterfeiting violations. ICE also draws heavily upon relationships with law enforcement partners throughout the

world. ICE special agents are deployed to 56 overseas Attaché offices, which makes it possible for ICE to effectively conduct global investigations.

ICE agents in the United States and abroad also work closely with the ICE Cyber Crimes Center (C3) to combat the problem of counterfeit pharmaceutical violations over the Internet. C3 is a state-of-the-art center designed exclusively for conducting computer-based investigations and providing expertise, computer forensics and investigative tools to investigators targeting Internet violations.

ICE also hosts the National Intellectual Property Rights Coordination Center, which maintains an on-going, open dialogue with the pharmaceuticals industry to exchange information and to serve as the primary point of contact for law enforcement referrals.

Another way in which ICE combats pharmaceuticals smuggling is through targeted operations such as Operation Apothecary. ICE initiated this operation to target and dismantle organizations involved in the illegal importation of commercial quantities of illicit pharmaceuticals. This initiative concentrates on illegal foreign- and domestic-based pharmacies and organizations involved in the smuggling and distribution of counterfeit prescription drugs and controlled substances. As part of Operation Apothecary, ICE agents conduct enforcement actions, in conjunction with CBP, FDA and DEA, at international mail facilities and express courier hubs to target and examine packages containing falsely declared or undeclared pharmaceuticals. ICE uses the

information obtained from these examinations to identify and target foreign sources, domestic organizations and recipients involved in such criminal activity.

Since 2003, ICE has initiated 178 criminal investigations of pharmaceutical smuggling. To date, these investigations have led to 86 arrests, 95 indictments and 34 convictions. Millions of dosage units of counterfeit, adulterated, misbranded and unapproved pharmaceuticals have been seized. ICE also conducts parallel asset identification and removal investigations, in conjunction with criminal investigations. ICE strives not only to put the criminals in jail, but also to remove the profit incentive.

ICE also participates in the Interagency Pharmaceuticals Task Force, which is composed of CBP, ICE, FDA, the Department of Justice (including the DEA), the Office of National Drug Control Policy, and the United States Postal Service (USPS). This task force fosters mutual cooperation among the responsible agencies in the regulation and enforcement of laws governing prescription drugs that are illegally being imported via mail and courier facilities.

**WORKING WITH CHINA**

ICE has actively engaged the Chinese Ministry of Public Security to conduct investigations of mutual interest. This dialogue led to the first two joint U.S. - China enforcement actions ever to take place in the PRC. One of these investigations began in February 2005, when the ICE Attaché Beijing received information that Richard Cowley of Shelton, Washington, was linked to groups of individuals involved in the sale of

pharmaceuticals in the United States and Europe. This information led to the initiation of Operation "Ocean Crossing", which targeted counterfeit pharmaceuticals being distributed via the Internet. ICE special agents, acting undercover, met with Cowley and learned the identity of his supplier in the PRC. Information from this investigation was shared with Chinese authorities, who then took action against the largest counterfeit pharmaceutical operation in China. ICE special agents traveled to China to assist in the coordination of joint enforcement actions. A total of 12 Chinese nationals were arrested, and three illicit pharmaceuticals facilities were shut down during joint enforcement actions in August and September 2005. The Chinese seized finished counterfeit drugs, raw materials and production machinery worth approximately $5 million. Cowley was arrested in the United States while the second raid was underway in China; he eventually pled guilty to importing counterfeit drugs and is awaiting sentencing. This case is an excellent example of the value of cooperation and information sharing in combating transnational pharmaceuticals trafficking. We at ICE believe that this mutual cooperation will continue to produce significant results.

**CONCLUSION**

ICE will continue to aggressively apply our authorities to combat the transnational organizations that traffic in counterfeit pharmaceuticals. This concludes my remarks and I would be pleased to answer your questions.

Mr. SOUDER. I thank you both for your testimony.

Let me ask kind of a side question first that came up at a hearing we had last week in Colorado on meth.

When Congress passes a new law that is about to take effect, for example, on September 30th, on—it's a legal drug if it has pseudoephedrine in it, but we're restricting the quantities and requiring people to register, and this will now become national.

Has there been any discussion of what the logical market reaction is going to be? It appears in Oregon that they've gone to the Internet to bring in the pseudoephedrine for the so-called mom-and-pop labs. Oklahoma just appears to be bringing in crystal ice. Those were the first two States with pharmaceutical regulations. But does what you're talking about here, how would that be handled with a legal product that we're trying to control the dosage, in effect?

Mr. DELLI-COLLI. Well, from ICE's perspective, with responsibility for the meth, it's a different division than the counterfeit division.

Mr. SOUDER. But this is the pseudoephedrine that's legal. For example, many headache medicines that would now—now the quantity is handled differently.

Mr. DELLI-COLLI. I'm not familiar enough with the legislation to know how the implication of that drug would be affected. I believe it would be similar to an anti-pharmaceutical; it's going to be prohibited unless it's brought in by a manufacturer.

Mr. LUTTER. Maybe I can expand on that a little bit. Pseudoephedrine brought in across the border would be treated as an illegal, unapproved drug because it has not been reviewed by FDA.

Mr. SOUDER. But I'm not talking about raw pseudoephedrine, or ephedra, which we already control; I'm talking about the pills. Any headache medicine that 37 States are going through that process as of September 30th, the Federal regulation will put it behind a counter with people having to sign in, and you can only get a certain amount of it. Now the way to get around that law is to do what you do with other prescription drugs and try to move around the border. And I'm wondering, when we pass major legislation like this that's going to slam down in 50 States, whether there's been any discussion, because the logical market reaction is going to be sort of trying to move around the legal distribution. And whether or not some of the ways you're trying to address tracking and so on would be a way to do that? I'm just wondering whether you've had any discussion about meth, because this is a new change that could result in a big bump up in what you're dealing with. But there hasn't been a discussion, I take it.

Mr. DELLI-COLLI. Any time you restrict the domestic sale of—if the drugs that have the active ingredient that could be used to manufacture meth are put behind the counter and make it a little more difficult to obtain, anybody that wanted to do something inappropriate with those drugs would, I believe, resort to the Internet to find a supplier for that ingredient.

Mr. SOUDER. And your agency hasn't begun to look at that impact?

Mr. DELLI-COLLI. Other than the fact that we would anticipate that we would see an increase.

Mr. SOUDER. What currently—if I may move to Dr. Lutter—what currently are some of the major drugs that you would be dealing with in the range of what you're trying to control here?

Mr. LUTTER. With respect to counterfeit drugs generally, or with respect to——

Mr. SOUDER. Counterfeit drugs generally. In other words, to give just kind of an initial layout here, are we talking mostly people who are—are they common medicines? Are they prescription drugs? Are they illegal drugs?

Mr. LUTTER. There is a variety of similarities among the drugs that have been reported counterfeited in the past in the United States. First, they are typically high value. Some of them are lifestyle drugs. And third, some of them are relatively easier to counterfeit in the sense of being liquids, clear liquids rather than pills, which are difficult to counterfeit because they have to be manufactured in a manner that closely resembles the authentic product.

In terms of the products that we've actually seen counterfeited in the past, recent cases that have been closed include Lipitor, anticholesterol drug, Viagra and Cialis, which are well known from advertisements, Zyprexa, and also other products for HIV and for AIDS. Procrit was also listed as a counterfeit drug according to recent accounts.

So the common theme here is that they are drugs that are high value in the United States in terms of the market as a whole, and also relatively—some of them are relatively easy to produce in a manner that deceives trained pharmacists and physicians.

Mr. SOUDER. As I understood your testimony, you were moving—you said you felt they could move forward in December with the process?

Mr. LUTTER. A key announcement that we made on June 9th of this past year is that we would allow the stay of the PDMA regulations to expire in early December of this year. An implication of the expiration of that stay of the regulation and a discontinuation of the stay is that there would be additional clarity to stakeholders in the drug distribution chain about who is supposed to provide pedigrees and what exactly the pedigrees are supposed to contain. The PDMA itself, as you know, mandated that stakeholders in a drug distribution system pass pedigrees to whoever the buyer is, unless they are authorized distributors of record, the term of art in the statute. And an authorized distributor of record in the statute is someone who has an ongoing relationship with the manufacturer. What the regulation that we issued in 1999 does is it defines further what is meant by an ongoing relationship. As you can imagine, many stakeholders have asked us what is actually meant by that. So what our 1999 regulation does is stipulate that an ongoing relationship which makes a wholesaler exempt from having to pass a pedigree under the Prescription Drug Marketing Act is a written agreement with the manufacturer designating that wholesaler as an authorized distributor. And under those circumstances, the authorized distributor would not have to pass the pedigree.

Mr. SOUDER. Is that authorized distributor list going to be published?

Mr. LUTTER. I'm sorry?

Mr. SOUDER. Is the authorized distributor list going to be published?

Mr. LUTTER. Yes. Our regulations make the—ask the manufacturers to make visible upon request the list of authorized distributors of record.

Mr. SOUDER. So that's available to you?

Mr. LUTTER. And to anyone else who asks. They're also directed by our regulations to update it continually.

Mr. SOUDER. Could secondary distributors claim they had been purchased from an authorized distributor when they really haven't been?

Mr. LUTTER. Well, a secondary distributor who is not an authorized distributor of record would have, as mandated under our regs and the statute, to pass a pedigree. So the pedigree would stipulate where they acquired the drugs and allow for anybody who buys the drugs from them an additional assurance that it is a pharma legitimate source and has been handled by known entities.

Mr. SOUDER. One of the things that I was confused when you were finishing your statement and I was reading it as well, my understanding—I thought I heard you say that the focus should be high value, and you repeated that a minute ago, things that are easier to counterfeit and so on. Does this mean this isn't going to apply to all drugs? This is a phase in? Are you providing a list of what the process will be in December?

Mr. LUTTER. The decision that we announced in June is to allow the stay to expire in early December, and as of that point the regulation takes effect. We also issued——

Mr. SOUDER. For everything?

Mr. LUTTER. Yes. We also issued a draft compliance policy guidance, which is now open for public comment. And we intend to issue that in final form before December. The key purpose of the draft compliance policy guidance is to articulate for stakeholders how we will use our enforcement resources for the first year during which the stay—after which—during which the regulations have taken effect. And there are four basic criteria in the compliance policy guidance that articulate how we will use our enforcement resources. They are essentially that we will focus efforts on pedigrees for drugs which are high value, and that's because we believe that——

Mr. SOUDER. Are you going to specifically define what high value is? Are you going to name the different drugs or——

Mr. LUTTER. We have in the compliance policy guide listed examples of high value drugs, but not provided a definition. We've also listed drugs which have previously been counterfeited. And the reason that these are higher risk is that there is a track record. Counterfeiters have shown themselves to be interested in counterfeiting these drugs in particular for whatever reason.

The third criteria is that for new drugs there needs to be a reasonable expectation that they're likely to be counterfeited, such as, again, expectations of high value or ease of creating a drug which

is very similar to the genuine FDA approved article. And then the fourth one would be for other violations of law.

Mr. SOUDER. And taking an example that you referred to say of Lipitor; so what you're saying is that would be one that they would be expected to have a tracking. Are you saying that they would have to have RFID tracking with it, or paper tracking would be sufficient at this point? A pedigree.

Mr. LUTTER. The regulation and the compliance policy guidance are silent about the particular technology to be used in providing the pedigree. The pedigree must be passed by certain entities, and it must contain certain information. We believe that RFID technology would offer a relatively cost-effective way of ensuring proper pedigrees. We think it offers substantial advantages to many stakeholders who believe it's the most promising electronic pedigree available based on the discussions that we had with stakeholders in our public meeting on February 8th and 9th. A variety of technologies presented at that meeting, other examples which were other than paper include a bar code, even a two-dimensional bar code, and very interestingly from the perspective of many stakeholders were hybrid technologies, technologies that would couple, if you will, RFID and paper or RFID and a bar code. And the purpose of these technologies was it reflected a need to meet stakeholders needs, given that the transition to an RFID world, which many people believe is where the industry will ultimately end up, will not be instantaneous but will instead involve a certain period during which there would be a demand for a variety of products to provide pedigrees using different technologies.

Mr. SOUDER. Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman. And again, I want to thank you for holding this hearing.

Let me first of all quote from the Center of Medicines in the public interest. They predict that counterfeit drug sales will reach $75 billion globally by 2010, an increase of more than 90 percent. And so this is a real issue. And it's not just about the United States; it's about the world.

Second, I want to point out, I have in my hands here 50 RFID tags. These are available today at relatively low cost. And so the technology exists today.

I also have counterfeit proof packaging, which is available today. This is not something we're talking about 10 years from now, 5 years from now; it's available today.

More importantly, a lot of this technology is being used today. Unfortunately, it's being used mostly in Europe. And I don't think the Europeans are intrinsically any smarter than we are. If they can do that, certainly we can do that.

Dr. Lutter, I want to read from your testimony, and I will quote, "The FDA stated in the 2006 Task Force report that although significant progress has been made to set the stage for widespread use of ePedigree, this goal, unfortunately, will not be met by 2007. The FDA is optimistic that considerable momentum and interest in widespread implementation of ePedigree continue and remains committed to working with the stakeholders—and I want to underscore stakeholders—to make this happen. Stakeholders urged FDA not to mandate RFID in order to give the private sector time to

continue with developing standards that build the appropriate and necessary infrastructure. We listened to their concerns, and did not require RFID use at this time."

Dr. Lutter, I understand that the stakeholders are not particularly interested in doing this, and my sense is they have their own reasons for that. But I want to come back to, I understand that the conclusion was that this would be too hard to implement against all of the prescription drugs that are out there, which is why Mr. Burton of Indiana and myself have introduced H.R. 4829. And we would essentially phase in the implementation of this technology in the drug supply, starting only with the 30 most easily or most commonly counterfeited drugs in the United States.

Dr. Lutter, why wouldn't you just start small? I mean, you don't have to do this globally. Why don't we begin somewhere? I mean, the journey of a thousand leagues begins with a single step, and I think the first single step is to say, OK, this is the biggest problem, let's scratch where it itches. Why didn't you do that?

Mr. LUTTER. With respect to starting small, that approach is actually very similar to something that we've adopted in the compliance policy guidance that we've put out for public comment. In that sense, we're using our resources to focus attention on pedigrees for the drugs which are most likely to be counterfeited during the first year after the red will take effect.

With respect to RFID more generally, I think the question there is really the maturity of the technology and its readiness for immediate adoption on a widespread basis.

According to the testimony that we heard in the public meeting on February 8th and 9th, a variety of issues pertaining to standards had not yet been resolved, and these included questions such as the frequency, how to characterize the serialization, in other words, a unique number for each individual product, and what to do, for example, with privacy. That is not to say at the same time that RFID isn't very promising. What we were told at that public meeting is that they were very successful pilot projects done by several drug companies with wholesalers, and these pilot projects had been so successful that they were not ended or discontinued when the original completion date arrived. Instead, they were seen as so successful that they were continued in a realtime production and distribution environment that allowed the manufacturers and the wholesalers information about inventory and the location of all the products for business reasons, in addition to providing information about the pedigree that would be useful in complying with the PDMA.

Mr. GUTKNECHT. OK. I'll let you off on that. I'm not sure I completely agree. Because as I say, if you wait for all the stakeholders to agree on this, I think it's going to be a long wait.

Mr. Delli-Colli—and I hope I'm pronouncing that close to the right way—over the last year, we have read about—and I received a number of calls and e-mails and letters from folks in my district about prescriptions that they had ordered via the mail from pharmaceutical supply houses in Canada that have been intercepted by your office. Can you tell us about that, and can you defend that?

Mr. DELLI-COLLI. First of all, by way of explanation, my organization is Immigration and Customs Enforcement, and we conduct

the criminal investigations that are associated oftentimes with seizures that are made by Customs and Border Protection. So what you may be referring to is that drugs are being ordered over the Internet from Canada and coming in probably through mail facilities or courier hubs and being intercepted by CBP and subsequently seized. CBP is doing that because currently there is no legal way to import drugs over the Internet. The only way you can bring in prescription drugs personally is if you accompany the drugs into the United States and present a prescription at the border.

As far as my office, we would only get engaged with an investigation if we believe that those drugs were being imported for criminal purposes to be illegally distributed, and not specifically for just an end user.

Mr. GUTKNECHT. But if a senior citizen in Winona, MN, is ordering their Prilosec from Canada, do you consider that a criminal act?

Mr. DELLI-COLLI. It also depends. First of all, when you order something over the Internet, how do you know it's coming from Canada? I mean, just because there's a Web site that indicates that the site is in Canada, we find often times that many of these organizations are trying to disguise their existence——

Mr. GUTKNECHT. Let me interrupt that. When you say oftentimes, you mean most of the drugs? I mean, often is an interesting word, but words have meaning. We're talking about drugs that actually are being distributed by Canadian distributors that have been doing this for many years, that are well respected, and we have had no problems either with counterfeit drugs or with adverse reactions by the consumers. So when you say often, that's a misleading word, isn't it?

Mr. DELLI-COLLI. Oftentimes meaning within the context of the investigations that ICE conducts. And again, CBP is enforcing the regulations that currently exist. So the investigations that we conduct again are geared toward individuals that are illegally distributing drugs over the Internet. So I may be looking at, you know, a different cross-section of what we're dealing with because I am a criminal investigator.

Mr. GUTKNECHT. OK. Well, my time is expired, but we're watching this very carefully. And I think our own government is overstepping its legal responsibilities to American consumers. And the Congress, just for the record, has gone on record several times making it clear that we believe that law-abiding citizens who are buying drugs from—prescription drugs—from established sources that have demonstrated that they are responsible and are distributing the exact same FDA-approved drugs, the Congress has gone on record several times saying that is not, in the opinion of the Congress, the right or the responsibility of the Custom agents to do. And I wish—and I want to thank the chairman for having this hearing, and I wish we could have more hearings on this because I think American consumers are being abused, and I think law-abiding citizens are being treated like criminals for no reason. And I just want that in the public record. Thank you.

Mr. SOUDER. Thank you.

Mr. Delli-Colli, in your testimony you said that ICE investigations have not revealed instances in which smuggled counterfeit pharmaceuticals were destined for the legitimate supply chain. However, you state in Operation Apothecary that you dismantle organizations involved in the illegal importation of commercial quantities of the pharmaceuticals. Where were they destined?

Mr. DELLI-COLLI. The people associated with the distribution, we're referring to illicit importation, the ultimate end use of these drugs is, in the cases that we've investigated, are going to people that either can't—that would not be able to get a prescription for the drugs, are drug abusers, or just don't want to go to a doctor and apply for a prescription. We haven't had any—our investigations lead us to drugs that are being provided to wholesalers or distributors to be entered into the brick and mortar pharmacies in the United States; these are individuals that are using the Internet to acquire drugs that they wouldn't legally be able to obtain or choose not to bother going to the doctor or a physician, or are just looking for cheaper drugs without any concern as to where they're purchasing the drugs from. And then there are people then obviously involved in the distribution process that are involved in smuggling drugs into the United States, traditional ways, bringing them in trunks of cars, hand-carrying them through the airports, and then set up Internet sites in the United States and ship those drugs via the mail, via DHL, FedEx, things of that nature.

Mr. SOUDER. So you haven't seen any instances of the equivalent of doctor shopping in the sense of certain pharmacies? We had one pharmacy in my district that actually—a group of meth users had sent somebody to a school, then opened up a pharmacy that became a major distribution point for meth. In Florida, in a hearing on OxyContin, the Orlando Sentinal had published, and we had quite a discussion that all the OxyContin abuse had come from just six places in the whole State of Florida. You haven't seen that kind of set up type operations where——

Mr. DELLI-COLLI. Again, because we're ICE, we're focused at the border in the interdiction capacity. So there are probably things that are occurring domestically which would fit in that nature. And there are—we have some cases that are somewhat ongoing that involve, you know, actual physicians that are licensed to practice that write illegal script, but again, we just have not had the type of case where some unsuspecting person would walk into CVS and hand a prescription over, and drugs that we intercepted were destined to be put into that chain as if part of the real supply chain. However, our investigations are increasing, and I think the vulnerability is definitely there for that to occur in the future.

Mr. SOUDER. We are obviously having a hot political discussion in Congress and across the country about what to do with legitimate Canadian pharmacies and whether they should ship in the United States, but anybody who has visited Mexico knows and is on the Internet that there is not security. Have you looked into or do you have any idea or do you work with the RCMP to see about trans-shipment, and in fact whether there are people working with the Canadian address who are not in fact Canadian pharmacies, do they have licensed pharmacies that they actually know? We know how much they bring in and how much they move out, and the

quantity of goods coming in from Canada exceeds the amount that they have in their supply chain. So the question is, is ICE looking at this mismatch, and do we actually know whether there is trans-shipment, or is this occasional or frequent?

Mr. DELLI-COLLI. Again, we believe that there is trans-shipment occurring via Canada as well. Again, what we're seeing and what we're getting—where our investigations are taking us is oftentimes we will either begin a case on the Internet or we'll find a package that is seized at the airport, and to defend my brothers at CBP a little bit, most oftentimes when they are seizing pharmaceuticals coming into the United States, they're falsely declared. They're not declared as drugs. They're declared as documents. They're not contained in the original packaging of the drugs. They've been removed from the blister packages, and they're inserted inside books and things of that nature.

So a lot of what we're seeing are blatant attempts to circumvent the regulations at the port. We don't necessarily know at the time we make those seizures who the supplier is; oftentimes we have to followup with interviews of people, not intending to necessarily prosecute them because it's just a personal use situation, but to ask them how they acquired it and then try to work those cases back. But we're seeing again that most of what we're seeing is the Internet is the primary tool for the distribution network.

Mr. SOUDER. When you find counterfeit drugs from China or India, which are two of the countries that you mentioned in the question—some from Mexico—who are they selling through? If it's predominantly Internet means, what kind of name would you look in the Internet to find it under? Is it pretending to be an American pharmacy, a Canadian pharmacy? What is the masquerade that they're using to ship the drugs in? Are they selling it on street corners through Lipitor gangs? I mean, I'm trying to sort——

Mr. DELLI-COLLI. Probably the least of those would be standing on the street corner. Those days are sort of behind us because of the Internet. It could be any of those. Oftentimes, obviously, if you're gearing toward the U.S. market, you're going to have an Internet Web site that is all done in English. It doesn't necessarily mean that—the site may purport to be in a foreign country, and it will just have information on there which makes it—purports to be tied to a legitimate brick and mortar pharmacy somewhere. It will indicate that it accepts all forms of credit card purchases, MasterCard, Visa, Discover. They will frequently ask questions, talk about how—with respect to the question they have about the drugs. They may even have a consult with a physician, but you just don't know who necessarily you're dealing with; that is the biggest problem.

We had one site—this is going back a few years, the end of 1999—we had a Thai site that, by all appearances, the site looked really legitimate, except it turns out that the person that was filling the prescription was buying the drugs out of the back of a brick and mortar pharmacy in Thailand and then was himself a hepatitis patient who just recently, when we did the enforcement act, had just recently got released from the hospital. And his assistant that was helping him fill the prescription was a Thai prostitute. So there's no controls over the quality or how these drugs are coming

in. And I think that's the dilemma that you get into, you know, who is regulating all these sites all over the world with respect to accounting for the legitimacy of those drugs.

Mr. SOUDER. Dr. Lutter.

Mr. LUTTER. If I could elaborate a little bit on the lack of controls. I have an example here of counterfeit Tamiflu that was purchased by—it was seized by Customs, who is not with us today, in April 2006 and turned over to the FDA Office of Criminal Investigations for investigation. OCI determined, the Office of Criminal Investigations at FDA determined that this had been purchased over the Internet by an NBC Dateline producer and was part of an order of 500 total capsules that was shipped from China. These products, as you see, are very similar to authentic Tamiflu. The labelling in fact is not so close to U.S. Tamiflu as to confuse trained U.S. physicians or pharmacists.

OCI is continuing its investigation into the source of this counterfeit, but the analysis of our forensic chemistry center confirmed that the packaging and capsules are counterfeit. And the capsules have no active ingredient. So aspects of this investigation, such as the source of the counterfeit Tamiflu, are still under investigation by OCI field offices, and for that reason the numbers on the blisters on the boxes are concealed here. But this is an example of how counterfeit products are available on Internet sites that Americans have access to.

Mr. SOUDER. The big question that I am still kind of wrestling with here is that, because the distribution system question is critical, because if that had an RFID or a tracer on it, it wouldn't really matter because that is not going to have one and it is not moving through regular tracking procedure. What is this pedigree? How is the pedigree going to affect the elicit market?

Mr. LUTTER. There are probably three related issues on that. In this instance, the U.S. purchaser was attempting to buy large quantities as if he were in fact a wholesaler, trying to sell to retailers and not for personal consumption. However, the Web site could be available also to individual citizens who would be buying Tamiflu, which is known to be safe and effective when used as directed not only against seasonal flu, a very important ailment that affects millions of Americans annually, but also against pandemic, which is a very serious threat that concerns the administration and many informed people in the public health community.

So the availability of the counterfeit Tamiflu for sale poses, either at a wholesale level——

Mr. SOUDER. But getting back to the question, that Tamiflu is already illegal, right? Is that package you just held up illegal?

Mr. LUTTER. I'm sorry?

Mr. SOUDER. Is that illegal?

Mr. LUTTER. Yes, this is illegal because it is counterfeit.

Mr. SOUDER. And if I as an individual went to the Internet to try to buy that, am I going to have a way to tell whether it's got a pedigree if I buy it off the Internet and it's not, because that's already illegal, having a pedigree isn't going to affect that?

Mr. LUTTER. A pedigree would not protect you. A pedigree is for the purposes of ensuring integrity of the wholesale distribution scheme.

Mr. SOUDER. And these people are outside that.

Mr. LUTTER. And these people are outside that. The pedigree provides an opportunity for U.S. wholesalers all the way through to dispensers, pharmacies or hospitals to verify that the product in question had an appropriate and valid chain of custody going all the way back to the manufacturer.

Mr. SOUDER. So in the 16 percent that I referred to in my opening statement, how much of that potential 16 percent or whatever the current figure is—that was a 2010 projection—that 16 percent is outside the chain of legitimate distribution, that we're not going to——

Mr. LUTTER. The number I think you referred to is 16 percent from mail order in the United States currently, and that reflects all sources, including Internet and old-fashioned mail order where people may not use the Internet. I don't know what percent of that is from foreign-based Internet pharmacies. We reported, HHS reported in a drug importation report to Congress in December 2004, that the total volume of imported parcles containing unapproved foreign pharmaceutical products was 10 million in calendar year 2003 and that contained approximately 25 million prescriptions. But these are rough estimates at best based on the experience that our staff have at international mail facilities.

Mr. SOUDER. Mr. Gutknecht, do you have any more questions?

Mr. GUTKNECHT. Mr. Chairman, not so much a question but I think there is what I would describe as almost a convenient conspiracy here. On one hand, you have the pharmaceutical industry who wants to hold American consumers captive. Counterfeiters don't counterfeit $1 bills. It is mostly $100 bills they counterfeit because it is worth doing.

The reason we have created this counterfeit industry is in large part because drugs in the United States are far too expensive. And what we have heard here is the Internet has become the instrument. Well, what is the Internet? It is the information age. And until American consumers knew how much more they were paying for the same drugs, they weren't interested in buying their drugs over the Internet. But once they began to know, once the information age—you can't hold American consumers hostage, and that is the fact. You can try, but it doesn't work and so now you have created a monster. And the answer, the technology that has existed now for a number of years, the FDA continues to decide, well, yeah, but we really, yes, it might work, but we don't want to use it yet.

And so now you have part of the conspiracy is the custom agents who are literally, for senior citizens who are dealing with pharmacies that they have dealt with for several years and bought their prescription drugs and they're completely satisfied and they believe and everybody believes they are getting exactly what they requested—incidentally, Governors are now on the other side.

Our own Governor of Minnesota, the Governor of Illinois, other Governors are saying, to save money, they want them to buy from certain prescription drug suppliers that they have screened. They have literally gone up and met with the people and looked at their operations and so forth and they have given them their seal of approval. But we have created this monster. And until or unless our government understands that you cannot hold American consumers

hostage in the information age, this problem is going to get worse and worse and worse. And the responsibility for that problem rests with the FDA, with Customs and with us.

So I want to thank you for coming to testify, but we won World War II in 3.5 years. We have been working on this issue of figuring out ways that Americans could have access to affordable FDA-approved drugs from FDA-approved facilities, we have been working on this for 5.5 years, and we won World War II in 3.5 years. And for me and I think for a lot of American consumers, this is totally unacceptable.

I yield back.

Mr. SOUDER. I thank you each for your testimony. We may have some additional written questions. Thank you for coming today. Thank you for your work. We will continue to track to see how this implementation works.

If the second panel could come forward.

The second panel is Carmen Catizone, the executive director of the National Association of the Boards of Pharmacy; Susan Winckler, vice president of policy and communications, American Pharmacists Association; John Gray, president and CEO of the Health Care Distribution Management Association; and Rick Raber, project manager, Northern Apex RFID.

It is our standard practice as an oversight committee to swear in each of the witnesses. Mr. Catizone, you are sitting in Mark McGuire's seat, so we do expect you to talk about the past anyway. Will you each raise your right hands?

[Witnesses sworn.]

Mr. SOUDER. Let the record show that each of the witnesses responded in the affirmative. Thank you for agreeing to participate in today's hearing.

Mr. Catizone, is that the correct?

**STATEMENTS OF CARMEN CATIZONE, EXECUTIVE DIRECTOR, NATIONAL ASSOCIATION OF BOARDS OF PHARMACY; SUSAN C. WINCKLER, ESQ., VICE PRESIDENT, POLICY AND COMMUNICATIONS, AMERICAN PHARMACISTS ASSOCIATION; JOHN M. GRAY, PRESIDENT AND CEO, HEALTHCARE DISTRIBUTION MANAGEMENT ASSOCIATION, HDMA; AND RICK RABER, PROJECT MANAGER, NORTHERN APEX, RFID**

**STATEMENT OF CARMEN CATIZONE**

Mr. CATIZONE. Yes, sir.

Mr. SOUDER. We will start with you.

Mr. CATIZONE. Thank you, Mr. Chairman, good morning.

Good morning, Representative Gutknecht.

Thank you for the opportunity to appear before you this morning.

I am pleased to report that significant progress has been made to combat the threat of counterfeit drugs. However, as far as we have progressed, there is still much to do before we can rest and maintain the confidence we have in the integrity of the medication distribution system for U.S. patients. The real threat of counterfeit drugs at this time is not the limited breaches which have occurred but the potential catastrophe that could result if the U.S. medication distribution supply system is compromised.

A recent incident that just came to our attention happened yesterday, where investigators in Indiana discovered counterfeit drugs that made their way into Indiana pharmacies from a wholesale distributor in Cincinnati. As we speak investigators are trying to track those sources and determine how widespread that counterfeit breach is.

If the U.S. medication distribution system is compromised, every medication that travels from the pharmaceutical manufacturer to the wholesale distributor to the pharmacy to the patient will be in question. If that is allowed to take place, no patient will be safe. In order to prevent that from occurring, the State Boards of Pharmacy and States have passed, are continuing to pass and implementing legislation that tighten the laws and regulations for the licensure and regulation of wholesale distributors. This concentrated and concerted effort is closing avenues for the introduction and diversion of counterfeit drugs and has already resulted in the end of operations for a number of wholesale distributors that were dangerous and seeking to corrupt our distribution system.

What has also propelled this effort is the shared desire of the pharmaceutical manufacturers, primary source wholesale distributors and technology vendors to work with the State Boards of Pharmacy and FDA to stop the influx of counterfeit drugs. Everyone involved in all aspects of dispensing and distributing medications to patients accepts the seriousness of the challenge and the crises or problems that could lay ahead.

I am also pleased to report that NABP's accreditation program for wholesale distributors is fully operational and is required to recognize by an increasing number of States. VAWD, verified accreditation of wholesale distributors, certifies that the wholesale distributor is legitimate, duly licensed in compliance with State and Federal laws, and adhering to criteria for the wholesale distribution of medications that protect the integrity of the system and patients receiving medications. NABP will accredit all wholesale distributors, licensed or seeking licensure in the State of Indiana. And since an overwhelming majority of wholesale distributors conduct business in multiple States, that accreditation system required by Indiana is fast becoming a uniform and national standard.

Some recommendations and considerations we ask of the subcommittee at this time to support the efforts of the States and sustain the progress being made are as follows: one, a uniformed pedigree system or auto tracking system must be established. It is a travesty that we can track the ingredients in the pizza prepared by our local pizza parlor better than we can track prescription drugs in the distribution supply system. Two, paper pedigrees are not a solution for counterfeit drugs. The counterfeit drug dealers are far too savvy and technology sophisticated to allow for much confidence in the paper-based system. The answer lies with the electronic track-and-trace technology, and we request support for the FDA to assume a leadership role in this area and use its expertise and influence to cause the development of the uniform standards and implementation of track-and-trace technologies and RFID as quickly as possible.

Third, we ask support for the implementation deadlines for RFID technology that the States are now enacting. Without a uniform

standard, without a uniform implementation date, the States are fast creating a patchwork of deadlines that are not supporting a uniform system. We need assistance. We need some uniform or national standards.

Thank you again for this opportunity. NABP and the State Boards of Pharmacy take the threat of counterfeit drugs very seriously and are doing all we can to maintain the integrity of the U.S. medication distribution system. We are working as hard as we can to help the States protect the health and welfare of U.S. patients. Thank you.

[The prepared statement of Mr. Catizone follows:]

# COUNTERFEIT DRUGS AND STATES' EFFORTS TO COMBAT THE PROBLEM

TESTIMONY BEFORE

SUBCOMMITTEE ON CRIMINAL JUSTICE,
DRUG POLICY AND HUMAN RESOURCES
COMMITTEE ON GOVERNMENT REFORM

July 11, 2006

By:
Carmen A. Catizone, M.S., R.Ph., D.Ph.
Executive Director
National Association of Boards of Pharmacy
July 2006

The distribution of medications in the United States from pharmaceutical manufacturers to wholesale distributors to pharmacies and ultimately patients is the most efficient and safest in the world. Although the US medication distribution system is unquestionably safe and secure, recent challenges confronting federal and state regulators to maintain its safety and security are growing and significant. The challenges are further complicated by the illegal importation of drugs, erosion of state and national borders, and a complete disregard for US federal and state laws by entities engaged in the production and distribution of counterfeit drugs.

For state boards of pharmacy, the government agencies constitutionally charged with regulating an ever changing and more complex practice of pharmacy with diminishing resources, the situation is at times is critical. The situation is further exacerbated by the reckless actions of local, state, and federal public officials who ignore public health and safety in order to promote the illegal importation of drugs as a item of political pandering. If the illegal importation of drugs continues, public safety experts contend that the US medication distribution system will be compromised by the influx of illegally imported products leaving state and federal regulators powerless to protect US consumers from the dire situation of a medication distribution system that cannot provide legitimate medications to its patients. If this situation occurs, no one will be protected, no one will be safe.

The National Association of Boards of Pharmacy (NABP) is playing a critical role with the states in trying to block the onset of such a catastrophe. NABP and the state boards of pharmacy are also reshaping state regulation of wholesale distributors to maintain the security and integrity of the US medication distribution system through the development and implementation of more stringent laws and regulations for the licensure and regulation of wholesale distributors. NABP is the international association for the state agencies that regulate the practice of pharmacy. NABP's members include all of the state boards of pharmacy in the United States, the District of Columbia, Puerto Rico, the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. NABP develops and administers the pharmacist licensure examinations and competent assessment mechanisms for the US boards of pharmacy, facilitates pharmacist licensure transfer among the states, and offers other programs and services to assist the state boards of pharmacy in developing state laws and regulations and the protection of the public.

## A SAFE DISTIRBUTION SYSTEM

An accurate assumption that patients can make at this time is that the medications which they receive from their pharmacist are safe and effective. The assumption is true because of the Food and Drug Administration's (FDA) oversight of the drug approval process and regulation of manufacturers and state regulation of pharmacists and pharmacy practice through state boards of pharmacy. In fact, just a few years ago, no one would ever have questioned whether the medication dispensed to them by their pharmacist from their local

pharmacy could be a counterfeit or fake or dangerous drug, particularly if that product flowed through the acceptable distribution channels for US medications. It is a rather recent and new assumption that holds if people ordered medications from the Internet or from sources outside of the normal distribution of pharmaceuticals, then people are exposing themselves to unknown and dangerous risks and the high probability of receiving a counterfeit drug.

## THE INCIDENCE OF COUNTERFEIT DRUGS

Reports from the FDA and World Health Organization (WHO) estimate that the incidence of counterfeit drugs is a growing concern in the United States and the world and define a counterfeit drug as "a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark...of a drug manufacturer, processor...or distributor other than the person...who in fact manufactured, processed...or distributed such drug and which thereby falsely purports or is represented to be the product of.... such other drug manufacturer, processor...or distributor[1]."

The estimates of the prevalence of counterfeit drugs released from the WHO and FDA vary from country to country but sound a similar concern. The concern is quite alarming particularly when the estimates of counterfeit drugs range as high as 40 – 60% for some African, Latin, and South East Asian countries. Data collected and released by WHO indicates that counterfeit drugs are more prevalent in developing countries than in industrialized countries. And although precise data are not available, some experts have estimated that up to 10% of our total international drug supply may be counterfeit. Some startling examples include the receipt in 1995 by a West African country of a gift of 88,000 doses of counterfeit meningococcal vaccine from Nigeria which may have contributed to 2500 deaths. And in 1998, the resulting pregnancy of approximately 200 Brazilian women as a result of a counterfeit oral contraceptive, the "active ingredient"....wheat flour, that surfaced in Brazil.

According to the FDA, counterfeit drug investigations conducted by the Agency averaged about 5 cases per year up to an including 2000. However, since 2001, this average has increased to 34 investigations per year with a significant spike in cases during the 2004 year. Although most of the cases involving counterfeit drugs were products distributed via the internet or black market, some counterfeit drugs have been found in the legitimate US medication distribution system. Increasingly, these investigations have involved well-organized criminal operations that seek to introduce finished drug products that may closely resemble legitimate drugs yet may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated. Thus, drug counterfeiting poses real public health and safety concerns today, and may pose an even greater threat in the future if we fail to take preventative measures now. As counterfeiters continue to seek out new technologies to make

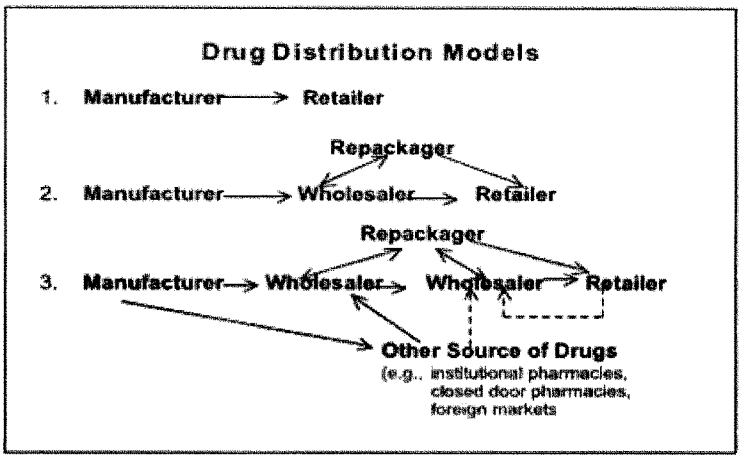
[1] US Food, Drug, and Cosmetic Act.

deceptive products and introduce them into legitimate commerce, our systems for protecting patients must respond effectively."[2]

Overall, the FDA believes that counterfeiting is not widespread within the system of manufacturing and distributing pharmaceuticals legally in the United States, as a result of an extensive system of federal and state regulatory oversight and steps to prevent counterfeiting undertaken by drug manufacturers, distributors, and pharmacies.

In a presentation to the Drug Information Association in Ottawa Canada in November of 2003, then FDA Commissioner McClellan noted that, "we're facing more serious international threats from criminals and profiteers who are trying to make a fast buck by going where the money is – which increasingly means prescription drugs and other medical products. We're seeing international counterfeit drug operations that are increasingly sophisticated and criminal networks that are better organized than ever before."[3] Information contained on the FDA web site illustrates the complexity of this issue and the ability of counterfeiters to duplicate products and product packaging. For the unknowing and unsuspecting patient, detecting counterfeit drugs is for all practical purposes impossible.

Counterfeit or diverted products are introduced into the supply system by several methods:




[2] Food and Drug Administration, COMBATING COUNTERFEIT DRUGS: A Report of the Food and Drug Administration, February 2004.

[3] McClellan, Mark B. Food and Drug Administration (FDA). Speech before the Drug Information Association. November 18, 2003, Ottawa, Canada.

In the most direct system, the manufacturer directly ships products to the retailer, be it a pharmacy, hospital or other institution. A variation of that direct delivery model ships the product from a pharmaceutical manufacturer to a primary wholesaler and then to the pharmacy. The remaining models, which probably represent the most vulnerable of the entire distribution system has limitless variations and allows for a number of potential entries for counterfeit and diverted drugs: Product is shipped by a pharmaceutical manufacturer to a wholesaler, either a primary wholesaler or secondary wholesaler, for entry into the distribution system and a maze of secondary and primary wholesale distributors. The overall lesson that has been learned is that as the number of entities handling the product increases, the chance of introducing a counterfeit or diverted drug may also increase.[4]

## THE PDMA AND COMBATING COUNTERFEIT DRUGS

The Prescription Drug Marketing Act of 1988 (PDMA), was signed by President Reagan on April 22, 1988, and enacted to ensure that prescription drug products purchased by consumers would be safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs could be sold to the American public. Congress decided that legislation was necessary because there were insufficient safeguards in the prescription drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and that a wholesale drug diversion submarket had developed that prevented effective control over, or even routine knowledge of, the true sources of drugs.

The PDMA, and as subsequently amended, requires State licensing of wholesale distributors of prescription drugs; requires unauthorized wholesale distributors to provide purchasers a statement (also called a pedigree) identifying each prior sale of the drug; and with certain exceptions, prohibits the sale of, or offer to sell, prescription drugs that have been purchased by a hospital or other health care entity or that have been donated or supplied at a reduced price to a charitable organization.

NABP, under the direction of the state boards of pharmacy, helped to define the implementation of the PDMA and assist the states in addressing the regulatory challenges of state licensure of wholesale distributors. Some of the solutions offered by NABP to the states included:

1. The development of comprehensive Model Rules aimed at achieving uniformity in the state licensure and regulation of wholesale drug distributors; and
2. The introduction of NABP's Verified-Accredited Wholesale Distributor Program (VAWD), which provides states with resources and a mechanism for inspecting and regulating wholesale distributors.

[4] Food and Drug Administration. FDA's Counterfeit Drug Task Force Interim Report, October 2003.

When the FDA issued proposed regulations for the implementation of the PDMA in the early 1990's, the agency received significant feedback from Congress and the wholesale distributor industry voicing concern that the pedigree requirements would create undue hardship on wholesaler distributors who did not receive product directly from the manufacturer. These entities, termed secondary wholesale distributors, argued further that it would be difficult for secondary wholesale distributors to obtain an ADR (Authorized distributor of Record) status from manufacturers (the ADR status would, in effect, exempt the requirement to pass pedigrees). A related and subsequent concern raised by the secondary wholesale distributor industry contended that primary wholesalers would probably not provide pedigrees to secondary wholesalers therefore prohibiting the secondary wholesalers from further distributing the drug. The arguments from the industry and successful lobbying efforts delayed implementation of the pedigree requirements till 2006. In June 2006, the FDA released a report on counterfeit drugs and removed the stay from implementation of the pedigree requirements.

## NABP MONITORING AND FINDINGS

NABP and the state and federal regulatory communities continue to focus on the public health hazards of counterfeit and adulterated drugs entering the US distribution system. These medications often reach US consumers when a patient orders the drug from a Web site, sometimes one alleging to be a US or Canadian site or allegedly connected with the US or Canada, or through the normal distribution system. Since 2004, NABP has participated in several Internet drug buy projects in order to illustrate the ready access consumers have to medications that should only be prescribed and monitored by a legal prescriber and tracked counterfeit drugs appearing in the legitimate distribution system.

### Controlled Substances and Isotretinoin

In December 2003 and January 2004, NABP in conjunction with a team from Dateline NBC purchased eight (8) different drugs from five (5) suspicious Internet pharmacy sites to demonstrate the ease with which dangerous drugs can be purchased without a prescription. Disturbingly, none of the drugs NABP received appeared to be shipped from the country in which the pharmacy Web site was registered and all of the drugs were labeled in a foreign language. The site offering Roaccutane® shipped the drug without proof of pregnancy testing or other evidence to determine if the therapy was appropriate, as is required by the US Food and Drug Administration (FDA) and legitimate medical practice.

After receiving the drugs, NABP sent the following items to the United States Pharmacopeia (USP) for identification testing:

- "Valium® 10 Roche, Tabletten Wirkstoff: Diazepam" (10 mg, #90 tablets)
- "Alprazolam Normon 1 mg Comprimidos EFG" (#30)
- "Codeisan" (30 mg, #40 tablets)

- "Roaccutane® isotretinoin 10 mg" (#30 capsules)
- "Testabol Depot® Testosterone Cypionate 10 ml For Intramuscular Injection" (4 x 10 ml vials, 200 mg/ml)

USP assays found that four out of the five drugs NABP submitted for testing contained the correct and appropriate amount of the active ingredient; however, two vials of the testosterone failed the USP's specification for potency (they only contained half of the dosage) and viscosity. These results indicated that one in five patients could receive drugs that are not full strength. It is important to note that USP performed limited testing; several other tests that could uncover potential dangers to patient health were not performed, including tests for contaminants resulting from preparation or poor packaging.

Anabolic Steroids

Over a four-week period beginning October 18, 2004, NABP covertly monitored several eBay auctions and purchased four products that were purported to be anabolic steroids. All four products were shipped from different sellers located within the US without the requirement of a prescription. One product was unique because it was advertised on eBay as a "Book of Test Propionate Sustanon" with the explanation that it was a "10 chapter unopened book" of useful information on testosterone propionate 100 mg.

NABP worked with MSNBC to have all of the products sent to an independent laboratory for analysis. None of the four products contained exactly what was expected. Error attributable to analytical factors, such as extraction efficiency or yield, is most likely to blame for the inconsistency in three of the samples. It is likely that these three products are the actual pharmaceutical products they claim to be. However, the fourth sample, which claims to be Sustanon 250 by Organon, is potentially a counterfeit product because the differences between the expected and actual contents fall outside the normal error ranges.

As a result of NABP's investigation, eBay tightened its rules and its monitoring process to eliminate the illegal sales of steroids on its Web site.

Similare Drugs

In late 2004, NABP collaborated with the pharmaceutical manufacturer, Eli Lilly, and FDA to evaluate Web sites that were allegedly selling prescription drugs that purported to be brand name medications or "similare" medications that claimed to be similar to or identical to their brand name counterparts, but, in fact, may have been subject to little or no testing or regulatory oversight. *Similares* are available in countries all over the world, particularly in Latin America, and are considered in many countries outside the US as legal and inexpensive alternatives to patented drugs. Further, these *similares* are threatening to enter or may already have entered the US drug distribution system through the Internet and other sources.

NABP ordered several different medications including Cialis®, Evista®, and Zyprexa® from a total of 13 Web sites. No prescriptions were required by the sites. FDA performed an analysis of the submitted medications; two, in particular, were highly suspicious.

Some of the sampled drugs far exceeded the level of allowed in the US medication. The amount of active ingredient present varied widely, and in at least one case, Fenilox (the "generic Evista"), no active ingredient was present. In addition, Lilly, the manufacturer of these drugs, performed a regulatory analysis on the products obtained by NABP and found that several were in fact *similares* and did not meet the company's US standards.

In May 2005, FDA issued a consumer advisory referencing the Evista that NABP purchased in addition to FDA's results from comparable tests on counterfeit versions of Lipitor® and Viagra® that were purchased in border towns of Mexico. Like the Evista *similare* in the NABP project, neither the counterfeit Lipitor nor the counterfeit Viagra contained any active ingredient.

## FDA'S TASK FORCE ON COUNTERFEIT DRUGS

On July 16, 2003, then FDA Commissioner Mark McClellan, M.D., Ph.D., formed an internal FDA Counterfeit Drug Task Force to develop recommendations for steps FDA, other government agencies, and the private sector could execute to minimize the risks to the public from counterfeit drugs and biologics compromising the U.S. drug distribution system. The initiative was designed to enhance the existing safeguards in place to protect the nation's drug supply from counterfeit drugs. Commissioner McClellan charged the Task Force with developing recommendations for achieving four fundamental goals: (1) preventing the introduction of counterfeit drugs, (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure of consumers to counterfeit drugs, and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs.

The task Force released its findings in October 2003 in an interim report. The Executive Summary noted that:

The Task Force reached several interim conclusions. First, there is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome than any single method. It could also be less costly, because a "one-size-fits-all" approach is unlikely to work for all parts of the complex prescription drug supply system. Second, although drug counterfeiters today are more sophisticated and better organized than ever before, there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats. While most of these new approaches have not yet been fully developed, implemented, and tested, they hold the promise of a more secure drug distribution system in the years ahead. Third, because many of these promising ideas have not been fully developed, the Task Force believes that an opportunity for broad public comment is essential to guide its further work.

The interim report contains a series of potential options that might be part of a multi-pronged approach to combat counterfeit drugs. The potential options are based on what

the FDA Task Force learned from reports, other governmental agencies, and individual stakeholders (e.g., state governments, trade associations, consumer groups, drug manufacturers, wholesale distributors, pharmacies, consumers, academicians, manufacturers of anti-counterfeiting technologies)[5].

## NABP TASK FORCES ON COUNTERFEIT DRUGS AND PEDIGREE REQUIREMENTS

NABP strongly supported the recommendations of the FDA Task Force and collaborated closely with FDA Officials to implement the Task Force's recommendations. NABP coordinated efforts with the FDA by commissioning its own task force to revise its Model Rules for the Licensure of Wholesale Distributors (Model Rules), which were originally developed in 1987. NABP's Task Force on Counterfeit Drugs and Wholesale Distributors convened in October 2003. The Task Force received input from industry stakeholders along with state and federal government agencies. The Model Rules were revised over the course of 4 months and released in February 2004, and acknowledged by the FDA. In response to various state activities and input from stakeholders, these Model Rules were revised in March 2005 and again in June 2006.

The NABP Model Rules released in 2006 contain regulatory guidance language for states to adopt which require submission of an extensive licensure application and criminal background checks, set standards for the operation and operations of wholesale distributors that, for example, prohibit entities from operating from their place of residence, mandate the appointment of a designated representative who is aware and involved in the daily operations of the wholesale distributor and serves as the principal liaison with the Board, and incorporates a criminal acts section with stiff penalties. Notable, in the Model Rules' criminal acts section, is the provision that if any act of this nature results in the death of a person, it constitutes a first degree felony.

The NABP Model Rules also require "Due Diligence" demonstration among wholesale distributors. In other words, wholesaler distributors must ensure that their transaction partners are legitimate and appropriately licensed and all transactions are legitimate. Wholesale distributors must also provide, as part of the due diligence requirements, copies of state/federal licenses, recent inspection reports, list of owners and operators, and other detailed information about the facility. They also must conduct criminal background checks on key employees, stock holders, and owners.

In January 2005, NABP convened the Task Force to Develop Recommendations on Electronic Pedigrees. The Primary objective of the Task Force was to gain consensus from state boards of pharmacy and other applicable state regulatory agencies regarding the necessary components for electronic pedigrees. The Task Force developed three major recommendations. First, the Task Force recommended that electronic pedigree records should include all transactions and distributions of a product beginning with

[5] Food and Drug Administration. FDA's Counterfeit Drug Interim Report, October 2003.

manufacturer until final sale and distribution to the pharmacy. Second, the Task Force recommended that implementation of electronic pedigrees by December 2007 was realistic and feasible. And third, the Task Force recommended the specific data elements for inclusion on electronic pedigrees.

## NABP'S VAWD PROGRAM

NABP launched the VAWD program in February 2005 as a result of its Task Force on Counterfeit Drugs and Wholesale Distributors' recommendations and in further support of the FDA's call for a coordinated state and federal endeavor to combat the threat of counterfeit drugs. VAWD was established to help protect the public from the threat of counterfeit drugs affecting the US drug supply.

NABP's VAWD program, accredits wholesale distributors who demonstrate compliance with the VAWD criteria which encompass - licensure, quality of the facility, personnel, recordkeeping, authentication/verification, the return of damaged and outdated products, and supported policies and procedures. The VAWD program provides assurance to the state boards of pharmacy and US patients that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions.

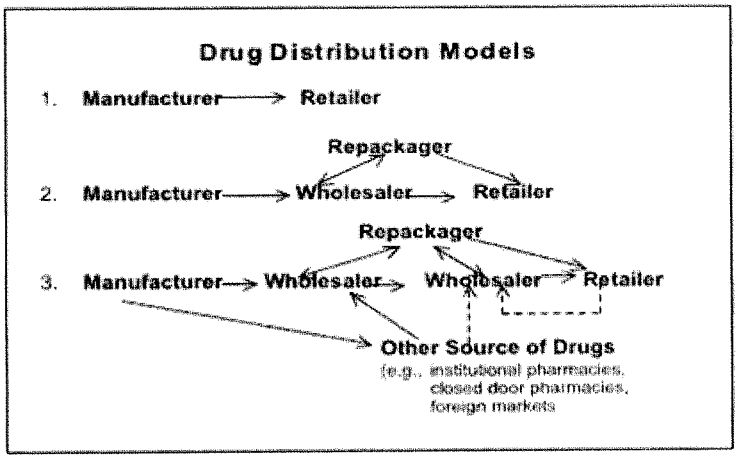
## CONCLUSIONS

NABP and the state boards of pharmacy consider the problem of counterfeit drugs a significant concern that must be addressed immediately and effectively. The present regulatory safeguards, which have been changed and strengthened in response to the FDA's Report on Counterfeit Drugs, require additional resources and support from state and federal legislatures to ensure that the US medication distribution system is not compromised.

The cooperation among the states and the FDA is also critical to the success of any effort to maintain the integrity and security of the US medication distribution system. The collaborations between the FDA, NABP, and the state boards of pharmacy to combat the threat of counterfeit drugs have been exemplary and continue to strengthen as new challenges are faced and new strategies developed. And, if state and federal regulatory agencies are supported by Congress and state legislatures in these efforts through increased resources and legislation, then the efforts to maintain the integrity and security of the US medication distribution system will be successful. If, however, the efforts of the state boards of pharmacy and FDA are not supported and the illegal importation of drugs is encouraged, then the US medication distribution system will be made vulnerable to the vagaries and dangers of an counterfeit and diversion network with tentacles

worldwide and with the devastating effect to afford little protection for US patients who depend on the US medication distribution system to live and survive.

Attachment A:



**STATEMENT OF SUSAN C. WINCKLER, ESQ.**

Ms. WINCKLER. Thank you, Mr. Chairman and the subcommittee for the invitation to appear this morning. We have heard already the foundation of data and statistics and numbers about the scope and problem and the threat of counterfeit medication.

For pharmacists, however, we don't consider counterfeit medications in terms of numbers. We consider them in terms of faces, the faces of patients with cancer, with asthma, with diabetes, our patients and the thought that our patients could receive a product that is at best of questionable effectiveness and at worst poison stops us in our tracks and raises the importance of what it is that pharmacists do to protect our system against counterfeit drugs to be of prime importance.

Pharmacists serve as the last line of defense in protecting patients from counterfeit medications. Recognition of this role however is not consistent. Our role and the impact of anti-counterfeiting initiatives on pharmacy practice is not always considered. We support enhanced efforts to combat counterfeiting, including advanced technology and coordination of efforts by all interested parties. Our support is tempered, however, by the need to minimize impact on our patients and recognizing the reality of the costs of these systems. Any anti-counterfeit initiative must include assessments of both the costs and benefits of those interventions.

As Congress seeks to close gaps in our system, it must assess the impact of any proposed solutions on pharmacists and our ability to serve patients. A little bit about the pharmacists role in this arena. We play three essential roles: the first as prudent purchaser; the second as an educator; and the third as a reporter of counterfeit products.

As a prudent purchaser, that's inherent. We have to be careful in whom we choose to purchase our medications from. But being able to do that well requires a licensure process and administration of that licensure process that is more than a paper fig leaf. We have to have confidence that the licensure process is more than making sure that the credit card or the check used to pay for that licensure process is valid. Our regulators need strong, clear regulations. They also need the authority to enforce those.

The pharmacist's role as educator may appear to be a little different, but this is where we help patients understand their role and what they need to do should they be presented with a counterfeit product and the risks that they in fact face. Pharmacists help patients understand that they need to report certain information to their doctor and to their pharmacist that might help us identify that counterfeit drug that has evaded all of us and unfortunately realized our worst nightmare, actually made it to a patient's medicine cabinet. And so we have to have that information about those counterfeit drugs in order to work directly with our patients.

An often overlooked side effect of counterfeit medications is the effect on legitimate medication use. As news of counterfeit medications emerges in the media, some patients stop taking their legitimate product because of fears about the product. For someone on blood pressure lowering medication or asthma medication, stopping that therapy could prove deadly. So we must also understand when we talk about counterfeit medication that we put it in the right

context and get information about that to the patients who may have been affected but help other patients understand the value of continuing their medication.

Pharmacists also have an important role in detecting counterfeit products, in noticing that the packaging may not be quite right or there is a difference in the appearance of the products and report that to the regulators so that we can protect those patients.

To do all three of these roles, we need some things. We primarily need access to information. We have to know when there have been counterfeit products, what are the risks? What is it patients should do? Because we translate the information that appears on CNN for the individual patient to help them understand what they need to do if they need to take any action.

We also need to have a consistent nationwide electronic pedigree. We support the FDA's recent recommendation to implement the relevant sections of the PDMA regarding the pedigree on December 1st of this year. As that implementation takes place, however, we do need to have consistent input and sufficient input from the stakeholders to make sure that implementation supports the eventual adoption of an electronic pedigree. And in this arena, PHA supports a strong national standard for the pedigree out of concern that having different State standards, while they may be intended to put a higher level of protection at the State level, may actually create loopholes that the unscrupulous operators would use to penetrate the system.

We also ask the subcommittee to consider the costs and liability of all of these systems and understand the roles that when we talk about anti-counterfeiting measures, it is not just the manufacturers, the wholesalers, but there are the manufacturers, pharmacists, wholesalers and, at the end of the day, the patients.

Mr. Chairman, as you mentioned, counterfeiting is often described as an economic issue, but we are stealing money from legitimate providers. Counterfeiting of drugs is so much more. It is stealing money. It is stealing health, and it is stealing our patients' confidence in our health care system, and we all must do whatever we can to stop that. Thank you.

[The prepared statement of Ms. Winckler follows:]

Statement
of the
American
Pharmacists
Association

**Submitted to the**
**House Committee on Government Reform**
**Subcommittee on Criminal Justice, Drug Policy, and Human Resources**

**On "Pharmaceutical Supply Chain Security"**

**July 11, 2006**


American Pharmacists Association
1100 15th Street, N.W., Suite 400
Washington, DC 20005-1707

(202) 628-4410
http://www.APhAnet.org

**Statement of Susan C. Winckler, RPh, Esq.**
**Vice President, Policy & Communications and Staff Counsel**
**American Pharmacists Association**

**Submitted to the House Committee on Government Reform**
**Subcommittee on Criminal Justice, Drug Policy, and Human Resources**

**On "Pharmaceutical Supply Chain Security"**

July 11, 2006

Chairman Souder, Ranking Member Cummings, and members of the Subcommittee, thank you for the opportunity to appear before you this morning and to present the views of the nation's pharmacists on the issue of securing our pharmaceutical supply chain. I am Susan C. Winckler, a pharmacist and an attorney, and Vice President for Policy & Communications and Staff Counsel for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA members provide care in all practice settings such as community pharmacies, hospitals, long-term care facilities, managed care organizations, hospice settings, and the military.

We commend the Subcommittee for reviewing one of the most critical, but largely unrecognized, issues facing our nation's health care system. Prescription medications are one of the most valuable weapons we have in our health care arsenal today. Unfortunately, because of their value, medications are highly susceptible to counterfeiting. With our current comprehensive federal regulatory system, few consumers perceive a threat from counterfeit medications – and for the most part, that perception matches reality. But counterfeit drugs *have* penetrated our system and we must increase our efforts to protect against future penetrations.

A pharmacist's worst nightmare is providing a patient the wrong medication or a medication that could harm them. We diligently review the accuracy and safety of prescriptions and intervene when necessary. But an even more troubling nightmare is presented by skillfully counterfeited medications. Our work is based on the underlying assumption that the medication we receive from the wholesaler or directly from the manufacturer is legitimate. In the counterfeit situation, the prescriber, pharmacist, and patient have done everything right—but the patient is at great risk. A counterfeit product contaminated with bacteria or poison, containing little active ingredient, or made with the wrong chemicals can cause great harm, permanent injury or disability, and even death. This is why pharmacists have considered anti-counterfeit activities a core of pharmacy practice. And APhA applauds the efforts of the Food and Drug Administration (FDA), the National Association of Boards of Pharmacy (NABP), drug wholesalers, and drug manufacturers to stem these illegal activities.

According to the FDA's 2004 Counterfeit Report[1], the number of counterfeit drug investigations increased four-fold from the late 1990s to 2004. These investigations discovered, for example, counterfeit Epogen®, Procrit®, and Lipitor® on pharmacy shelves and in patients' homes; and counterfeit Ortho Evra® contraceptive patches (with no active ingredient) being sold online by a company based in India. Additionally, a February 2006 World Health Organization (WHO) report[2] states that counterfeits are estimated to represent more than 10% of the global drug market — an estimated 25% of the medications consumed in developing countries. Furthermore, the Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005.

These statistics reflect a greater number of counterfeit drugs available for consumption, in the U.S. and elsewhere, and requires us to ask whether we can we continue to trust the drug products that we, as pharmacists, dispense to our patients. Can patients, pharmacists, and prescribers trust that the products we ingest, apply, or inject will do what they are supposed to do – and nothing they are not? That trust requires strong systems applied with vigilance, including developing mechanisms to better ensure that drug products are safe and that patient care will not be disrupted or damaged.

The protection of our medication supply, including efforts to prevent the introduction of counterfeit products into the system and the quick identification and elimination of such products from the system if the medication supply is compromised, is critically important to pharmacists, both as consumers and health care professionals. It is likely each one of us took some medication this morning—whether a prescription for a chronic condition or infection or perhaps an over-the-counter pain reliever for a headache. It is highly unlikely that we paused for even a second to consider whether than product contained everything it should and nothing it shouldn't. Hundreds of times a day, pharmacists similarly assume that a product that has gone through the 'normal' supply chain and that appears to be manufactured and labeled according to the FDA's specifications, is legitimate.

Pharmacists serve as the last line of defense in protecting patients from counterfeit medications. Recognition of this role, however, is not consistent. Our role and the impact of anti-counterfeiting initiatives on pharmacy practice are not always fully considered. APhA supports enhanced efforts to combat counterfeiting, including advanced technologies and coordination of efforts by all interested parties: including manufacturers, wholesalers, pharmacists, and patients. Our support is tempered, however, by the need to minimize the impact on our patients and recognizing the reality that as pharmacists, we are working with limited resources. Any anti-counterfeit initiatives must include assessments of both the costs and benefits. As Congress seeks to close gaps in our system, it must assess the impact any proposed solutions might have on pharmacists and our ability to serve patients.

---

[1] http://www.fda.gov/oc/initiatives/counterfeit/report02_04.html
[2] http://www.who.int/mediacentre/factsheets/fs275/en/

**Role of the Pharmacist**

Pharmacists fight counterfeit drugs in their three roles as:

1. Prudent purchasers,
2. Patient educators, and
3. Reporters of possible counterfeit activities.

*Pharmacists Fight Counterfeit Drugs by Being Prudent Purchasers*

As prudent purchasers, pharmacists limit their purchases to legitimate sources. Buying only from licensed wholesalers is essential, and the quality of that licensure process must be more than a simple administrative process. Our ability to identify legitimate providers is directly related to the legitimacy of the regulation of those entities. If a license merely confirms the validity of the credit card number or check submitted with the application, then the usefulness of the licensure is minimal.

Regulators must have adequate power and resources to assure that participants in the supply chain are held to a sufficient standard and eliminated from the system if they fail to meet that standard. And although we are often bombarded with solicitations for deals on medication, we also know that deals that sound 'too good to be true' likely are. Upon receiving the products, pharmacists and their staff review the shipments to ensure that the products have been handled properly and securely; and pharmacists are vigilant when storing products. In addition to counterfeiting risks, many medications can be affected by temperature, humidity, and light.

Our purchasing efforts require a strong, consistent regulatory system with clear coordination between the federal and state regulators. These regulators must have clear roles, authority, and resources to implement existing and any new anti-counterfeiting initiatives.

*Pharmacists Fight Counterfeit Drugs by Educating Patients*

As educators, we help our patients understand the medications they take and what effects to expect. We also help patients understand the need to bring certain information to the attention of their pharmacist and their doctor. While much of this education is relevant to the knowledge and skill generally necessary to make the best use of medications, patients also play a role in identifying and eliminating counterfeit medications. Just as pharmacists must be prudent purchasers themselves, the purchasing habits of patients play into this system. But patients who ignore this information by circumventing the US drug regulatory system circumvent its protections. Whether illegally importing medications from another country or frequenting a gray-market provider in their home town, patients themselves support the counterfeit system and increase their risk of taking a harmful or even deadly drug. Importation, particularly personal importation, raises patients' risk of receiving a substandard or fake medication substantially by exposing patients to drug providers who are often unregulated or at least regulated very differently. Members of Congress and state policymakers, in an effort to increase access to medications for their constituents, have begun efforts to facilitate importation. But few have addressed the increased risk of importing counterfeit drugs.

The FDA has reported[3] that spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. Assessing the quality of these products provided outside our regulatory system is challenging in the best of circumstances— where original manufacturer packaging is used and a licensed foreign pharmacy involved. Protecting against counterfeit products is extremely compromised when the products are improperly packaged and shipped loose in sandwich bags, tissue paper or envelopes, or are labeled inadequately, such as those with missing dosage information or labeling that is not in English.

To protect against the harm that may be caused by such products, pharmacists work with patients to help them understand the importance of reporting any changes they notice in the look and feel of their medication, its labeling, and its effect. While many changes in product appearance are the result of expected and regulated manufacturing changes, such differences can indicate a counterfeit product. Similarly, a difference in taste or feel may be nothing to raise concern or it may indicate a compromised supply chain. Bringing such differences to the attention of their pharmacist and doctor can help identify a fake product. But patients need to be aware of the importance of reporting and must know where to report — that they should tell their pharmacist when a drug looks, smells, feels, or tastes different than what they had previously experienced or expected. When a patient reports an atypical adverse reaction, unusual side effect(s), or unexplained treatment failure, pharmacists can use their clinical skills to rule out counterfeit medications.

An often over-looked side effect of counterfeit medications is the effect on legitimate medication use. As news of counterfeit medications emerges in the media, some patients stop taking their *legitimate* prescription medications because of fears about the product. For someone on blood-pressure lowering medicine or asthma medication, stopping therapy could prove deadly. Patients must understand their individual risk of having received counterfeit medication and the need to continue their current therapy. While media reports provide some of this information, the real education occurs between individual patients and their pharmacist.

If counterfeit medications are detected, it is pharmacists who field the vast majority of questions from patients about the products and the individual patient's risk of having received a counterfeit product as well as what risk might have been posed by the product. Essential to this role is receiving accurate information about the scope of the problem and potential effect on patients, as well as clear recommendations for action. This information must reach pharmacists and physicians at least at the same time such information is provided to the mass media. While CNN may be an excellent venue for providing information about the problem, it is the health care system that must provide the translation of that information for individual patients.

---

[3] Statement of John M. Taylor, III Associate Commissioner for Regulatory Affairs Food and Drug Administration before the Permanent Subcommittee on Investigations Committee on Governmental Affairs, July 22, 2004

One way APhA focuses on the importance of patient education is through American Pharmacists Month, an annual event each October where our public education campaign encourages patients to get to know their pharmacist and their medications — the name of their medication and why they take it, what their medication looks like and how it makes them feel — and to talk to their pharmacist if they notice any differences.

*Pharmacists Fight Counterfeit Drugs by Reporting Suspicious Activities to the Right Authorities*

Pharmacists regularly notify the FDA and other appropriate agencies of suspected counterfeit drugs. Pharmacists' visual confirmation of a problem with packaging, labeling, or the medication itself (capsule size, color, smell, etc.) may trigger a formal investigation of the product. To visually confirm legitimate drugs, pharmacists must stay abreast of changes in drug appearances, labeling and packaging. Reporting systems must be simple and easy to navigate to support reporting by pharmacists and other health care professionals.

**System Improvements that APhA Recommends Congress Facilitate**

*1. Access to Information*

Essential to fulfilling each of these roles is information. Without accurate and timely information, our efforts are thwarted. We must build upon successful systems and assure that agencies are sufficiently staffed to provide necessary communications. Some infrastructure exists today. In February 2004, the FDA created the Counterfeit Alert Network, a coalition of health professional and consumer groups to facilitate counterfeit drug-related communications. The Network has three goals:

- to disseminate alert messages to a wide audience about specific counterfeit drug incidents in the U.S. and measures to take to minimize exposure (recall information, for example);
- to develop educational information about the roles and responsibilities that consumers, pharmacists, other health professionals, and wholesalers should play to identify counterfeit drugs, report suspect counterfeit drugs, and prevent them from entering the U.S. drug distribution system; and
- to develop a network of national organizations, consumer groups, and industry representatives to help distribute the information.

In the event of a confirmed counterfeit case in the United States, FDA will send an alert to these partners. The agency also will send partners a notice if a counterfeit incident is confirmed elsewhere in the world that could affect U.S. patients. APhA is a member of this important collaborative effort. While we hope it is a resource that we will have little need to use, it is essential infrastructure to mitigating the damage of counterfeit products. To assure the success of this initiative, the Agency must have sufficient funding to support this infrastructure.

*2. Make Monitoring More Consistent, and Counterfeiting More Difficult, by Moving to a Nationwide Electronic Pedigree*

While pharmacists function as the last institutional protection in the prescription drug supply chain, protection against counterfeit products must occur at every step in the process. Effective protections require strong, consistent oversight. Each Member of this Subcommittee is likely familiar with a common anti-counterfeiting intervention: the pedigree, a mechanism documenting the movement of medication from manufacturer to the pharmacy or other distributor. Legitimate pedigrees provide pharmacists, pharmacies, and other members of the supply chain documentation of the medication's path within the distribution system. Having access to such information is essential, but the pedigree requirement must provide more protection than a paper fig-leaf. Counterfeiters capable of reproducing product labels and medications themselves are quite capable of counterfeiting the accompanying paper pedigree.

Our concerns with a paper-based system have not dissipated since the year 2000 when we submitted comments to the FDA on the topic, although our confidence in the distribution system has changed. A paper pedigree system could negatively impact the security of our drug distribution system by creating a false sense of security when the mere presence of a paper pedigree could be proof of little. A paper-based pedigree system may provide a track record of the product movement, or simply provide a counterfeit record of the product movement—a trail as fake as the product it accompanies. If an entity is sophisticated enough to counterfeit the product, the same entity would be equally capable of counterfeiting a paper pedigree. Additionally, pedigree requirements must be implemented in a manner that provides the highest degree of valid information with the least disruption to operations. Requiring members of the supply chain to produce and distribute massive amounts of paper that may or may not be legitimate is not a good use of resources.

APhA supports the FDA's recent recommendation to implement relevant sections of the Prescription Drug Marketing Act (PDMA) via regulations regarding the pedigree on December 1 of this year, providing necessary policies are in place. The Agency's Compliance Policy Guide on this topic must be fully discussed and finalized before implementation—and the interests of all stakeholders considered. Manufacturers and wholesalers must implement the 'authorized distributor' in a way that accommodates both parties and does not allow one of those participants to arbitrarily assign 'authorized' status. Any designation of vulnerable products must be carefully developed, and a clear articulation of the agency's enforcement priorities provided.

To facilitate the implementation of these requirements, APhA supports the premise that these standards be applied uniformly across all states. Allowing states to develop and enforce stricter pedigree requirements creates the potential for the opposite to occur: inconsistent requirements for products that we know will cross state lines inherently create loopholes that unscrupulous operators will exploit. While APhA is hesitant to support federal pre-emption of state health regulation in many areas because of the great

role state regulators play in pharmacy practice and health care generally, the anti-counterfeiting success of drug pedigrees requires federal pre-emption.

Finally, the path to implementing 'e-pedigrees' must be clear and supported by these interim efforts. Issues of technology standards, cost, and patient privacy must be addressed by all stakeholders to yield a consistent, quality process. Congress should support discussion and resolution of these issues. E-pedigrees hold great promise, but a coordinated effort is essential to cost-effective implementation.

*3. Implement Specific Anti-Counterfeit Packaging Protections*

Because counterfeiters have proven themselves sophisticated and adaptable to advances in technology and changes in anti-counterfeiting efforts, APhA supports the use of both covert and overt anti-counterfeiting technologies. While overt technologies, such as specific colors and fonts for labels, can provide pharmacists helpful clues about the validity of the drug they are dispensing, instituting only overt technologies could provide the counterfeiter a "blue print" on how to circumvent the system. Even as each type of anti-counterfeit technology, alone, provides a benefit, creating a system builds upon the strength of each technology and helps create a less penetrable system, because advantages and disadvantages exist with each type of technology.

For example, bar codes, a type of track and trace technology, are often discussed as an anti-counterfeiting technology that should be adopted industry-wide. Incorporating bar codes may provide many benefits beyond simply assisting in anti-counterfeit efforts, such as inventory control, reducing medication errors, identifying theft and diversion, and implementing recalls. The value of bar codes to anti-counterfeiting initiatives, however, must consider the ease of copying bar codes and circumventing the protections by creating fake bar codes. While still an important option for a base-line anti-counterfeit strategy, no single technology will prevent counterfeiters. Sophisticated criminal activities require sophisticated countermeasures.

Another example of packaging protections is unit-of-use packaging. APhA supports adoption of unit-of-use packaging as the industry standard[4] for a number of reasons including anti-counterfeit measures. A unit-of-use package is a container system designed to hold a specific quantity of a drug product for a specific use and intended to be dispensed to a patient without any modification except for the addition of appropriate labeling. Such packaging can help enhance patient safety, patient compliance, and efficiencies in drug distribution. Unit-of-use packaging, implemented with yet-to-be-established industry standards, can deter counterfeiting by supporting tracking of each patient-unit of product. Congress can help stimulate the adoption of unit-of-use

[4] The following policy statement was adopted in 2003 by the APhA House of Delegates: ***Unit-of-Use Packaging:*** APhA advocates for the adoption of "unit of use" packaging as the industry standard to enhance patient safety, patient compliance, and efficiencies in drug distribution. APhA shall collaborate with the pharmaceutical industry, third party payors, and appropriate federal agencies to affect the changes necessary for the adoption of "unit of use" packaging as the industry standard. APhA encourages the enactment of legislation and regulations to permit pharmacists to modify prescribed quantities to correspond with commercially available "unit of use" packages.

packaging by supporting the development of standards regarding the days supply, package size, and other necessary parameters.

*4. Fairly Distributing Costs and Liability*

We encourage the Subcommittee to consider that all anti-counterfeiting efforts affect the liability of supply chain participants. For pharmacists, it is important that the liability of the pharmacist equate with our liability in all other areas of practice—a standard of negligence. As health care professionals, we are (and should be) required to meet our responsibilities as that of a 'reasonable pharmacist' and our responsibilities in anti-counterfeiting efforts should be the same. Should counterfeit medications reach patients despite the best efforts of the pharmacists involved, those responsible for the counterfeiting should be responsible—not the health care professionals whose efforts were defeated by criminals. We commit to performing our roles within the health care system, but do not accept liability for the actions of others.

As noted previously, efforts to better protect our medication supply are necessary but the cost and practical implications of such efforts must be considered in identifying and implementing the right solutions. Technology advances present an opportunity to strengthen the safety of our drug supply. Pharmacists and pharmacies will bear some of the additional costs necessary to employ new anti-counterfeit technologies. Depending on the technology and the necessary equipment, this may involve a substantial financial contribution. While providing an anti-counterfeit benefit, the burdens associated with infrastructure upgrades must be taken into account as policies around anti-counterfeit technologies are developed.

**Conclusion**

Thank you for your consideration of the views of the nation's pharmacists. APhA applauds your review of this important issue given recent increases in counterfeit medications. Vigilance against counterfeit medications is necessary to mitigate the risk that ineffective and/or harmful drugs could reach the hands of our friends, our family or us. However, as the Subcommittee considers the steps to limit drug counterfeiting, the analysis must consider the costs associated with the recommendations – costs in terms of both time and money. Pharmacists and other members of the pharmaceutical supply system are ready to invest in appropriate measures, but we should invest wisely in those strategies that will provide the best value for the cost.

APhA looks forward to working with the Subcommittee to ensure the integrity of our drug supply and to help decrease the likelihood of unscrupulous operators preying on consumers through their medicine cabinet.

Mr. SOUDER. Thank you. Mr. Gray.

**STATEMENT OF JOHN M. GRAY**

Mr. GRAY. Thank you, Mr. Chairman. Thank you for the opportunity to provide some perspective here on behalf of HDMA and my 40 primary full service distributors.

We represent large national as well as numerous regional family owned companies. Our members deliver over 9 million health care products a day to about 142,000 locations which include pharmacies, hospitals, nursing homes, clinics and the like. HDMA and the members of our organization have particularly in the last 4 to 5 years begun working extremely closely with all our supply chain partners, from manufacturers down to pharmacies. We take the mission to work together cooperatively seriously. And we are supporting all the efforts to make sure that the U.S. medicine supply chain remains secure.

There is no greater concern I know, particularly in my term here from our board of directors, no greater concern among them as a group of companies, about the threat of counterfeit medicines and what they represent to the supply chain. In response to that concern, we have begun to look at this problem through four key areas that we think as an organization, as an industry need to be addressed: No. 1, strict regulation and enforcement of laws regarding counterfeit drugs; No. 2, current and emerging technologies and making sure those get employed; No. 3, business and government alliances to track and report the counterfeit drugs, and No. 4, developing and implementing industry best practices.

This morning, I will just address the first three of those four. The fourth is laid out in my detail in my written comments.

First and foremost on the regulation and enforcement arena, we have fully supported the implementation of the final PDMA rule as of December 1, 2006. We think it is time for this industry to move on and get that accomplished. We think it is a key part of any anti-counterfeiting strategy the industry employs going forward. But our position is, it is just one aspect of it.

In addition, we have worked extensively over the last years with the NABP, and we have worked and developed a model State licensure bill for the States to establish uniform tough standards on licensing wholesale distributors in the United States. We have been working with NABP and manufacturers, particularly this past year, in a number of States. I am here to report there are 16 States already enacting standards, including your State, Mr. Chairman. And there are bills pending in 18 other States currently. Our goal here is to make sure that no criminal ever gets a wholesale license to distribute drugs again in this country.

The final area, in regulation of the penalty enforcement, our belief is currently the current Federal penalties are inadequate and outdated. We are advocating for strong criminal penalties for counterfeiters. I believe there is legislation in the Congress today addressing that matter.

Then moving on to current and emerging technologies. We believe anti-counterfeit technologies are the most important tool we have available to try to secure the supply chain. No single technology would work. We think it is a layering of a variety of tech-

nologies. We hold the most promise out for this EPC RFID. We think that is the way the industry can go and probably likely will go to track and trace and authenticate products in the supply chain.

The ability of EPC to tie unique electronic ID to an item to track it and trace it throughout the supply chain we believe is critical. My personal past experiences come from the consumer goods industry. I can tell you the progress being made, although it may appear to some to be slow, having lived through the development of linear bar coding from 1970 and on, we have made lightening speed with EPC technology. I think the industry is moving along well in that effort.

As far as HDMA is concerned, specifically what we are doing in this organization, we are partnering with NACDS, our chain drug partners again for the second year in a row, and providing an RFID summit to bring all the industry leaders together to make them more clearly understand how to implement this technology and get those chips that Mr. Gutknecht has on these products and get them operating.

We are also working, our members are involved in a number of the pilot projects currently going on that have been announced publicly. Our education and research foundation I believe has taken on the crux of the issue as far as EPC, and that is data management. Having lived thorough this world before, it is one thing to employ technology; it is another to also manage the data that comes from that technology.

We are engaged with PHARMA as an organization and Rutgers University to look in-depth at how this industry will manage the data. Where is it going to go? Where is it going to reside? How will it be shared? How will law enforcement have access to it? Because all those rules, all those issues are terribly important, particularly when it gets into privacy issues with the consumers. So data management is critical as well as the technology. That is why I say it is a multi-layered approach.

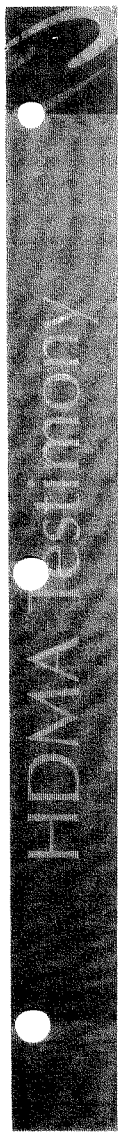
Finally, I would just say that as far as any of these things, patience is obviously required, but I think the industry is moving in the right direction. And I would agree with my other panelists here that, as far as uniform pedigree, one impediment to EPC right now is the lack of uniformity. If the industry gets bogged down in EPC and attracting not only all the data going beyond pedigree, all of the data that will be encompassed in EPC will be almost unbearable for the industry to deal with if we do not have uniform pedigree.

Finally, an alliance between NACDS and PHARMA, and we are working with the FDA in our counterfeit alert network, and we have also joined the RX Patrol which is a device by which we can report theft directly to customers and to members throughout the supply chain.

In sum, I will tell you, in my short time, we understand more than anybody the public trust placed upon our members to do this, to make sure the supply chain is authenticated and safely managed. We have zero tolerance as an organization as a philosophy for counterfeiters, and you have my pledge that we will remain constantly vigilant as a group of companies—that's 40 wholesale dis-

tributors—to make sure that this supply chain is as secure as the American consumers need it to be. I am available for questions. Thank you for your time.

[The prepared statement of Mr. Gray follows:]




# Statement of the Healthcare Distribution Management Association

## Presented by John M. Gray, President and Chief Executive Officer

## Before the House Committee on Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources on "Pharmaceutical Supply Chain Security"

## July 11, 2006

Healthcare Distribution Management Association (HDMA)
901 North Glebe Road, Suite 1000 • Arlington, VA 22203
(703) 787-0000 • (703) 935-3200 • www.HealthcareDistribution.org

HDMA
Healthcare Distribution Management Association

**Introduction**

Mr. Chairman and Members of the Subcommittee, thank you for the invitation to provide the perspective of the Healthcare Distribution Management Association (HDMA) at this important hearing on the issue of "Pharmaceutical Supply Chain Security." I am John Gray, HDMA's President and CEO.

HDMA represents the nation's primary, full-service healthcare distributors. Our members include large national companies and regional, family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 142,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system.

HDMA members serve as the central link in a sophisticated national supply chain. As such, we have a responsibility to work closely with our supply chain partners to safeguard patient safety. We take this mission very seriously, and we support manufacturers, pharmacies, law enforcement, regulators and legislators in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated. No one link in the supply chain works independently, and patients depend on our collective efforts to keep their medicine safe and secure.

**Ongoing Supply Chain Improvements**

There is no greater concern among HDMA members than the threat of counterfeit or adulterated pharmaceutical products in our healthcare system. Manufacturers, distributors, and pharmacies must remain vigilant in recognizing this increasingly sophisticated criminal threat, and must continually implement new systems, processes, and techniques to defeat it. While there is no single solution to the counterfeit threat, we believe any effective response must include:

1. strict regulation and enforcement;
2. adoption of new technologies;
3. business and government alliances to track and report counterfeit drugs; and
4. developing and implementing industry best practices.

***1. Strict Regulation and Enforcement***

HDMA advocated for the implementation of the Prescription Drug Marketing Act (PDMA) final rule as an important measure in the effort to combat counterfeit drugs. By implementing the Final Rule on December 1, 2006, we believe the FDA is taking an important step forward to further ensure patient safety, prescription drug integrity, and supply chain security. The pedigree provisions of the PDMA, however, are just one part of a comprehensive anti-counterfeiting strategy.

To that end, strong and consistent distributor licensure requirements are absolutely critical to ensure that criminals are **never** able to handle and distribute prescription medicines. Because the nation's drug distribution system is regulated at both the federal and state levels of government, HDMA proactively drafted a model state distributor

licensure bill two years ago with the goal of achieving uniform, tough standards on a state-by-state basis. We have worked closely with the National Association of Boards of Pharmacy (NABP) and manufacturer and pharmacy organizations to advocate for implementation of more uniform, tough standards. I am pleased that sixteen states have enacted tougher distributor licensing standards, including the chairman's home state of Indiana, and bills are pending in an additional 18 states.

HDMA is also a strong supporter of increasing criminal penalties for those involved in drug counterfeiting and medicine tampering. The current federal criminal penalties for those who are knowingly involved in the counterfeiting of prescription drugs are wholly inadequate given the potential harm that can result from fake or adulterated medicines. That is why HDMA has advocated for increasing criminal penalties and we support the "Counterfeit Drug Prevention Act" (HR 5156), introduced by Representatives Mike Rogers and Gene Green. HR 5156 would increase criminal penalties for counterfeiting prescription drugs from three years to 20 years, and life in prison if the counterfeiting results in death.

*2. Adopting New Technologies*

Anti-counterfeiting technologies can serve an important role in securing the nation's prescription drug supply; however, no single technology can absolutely prevent counterfeiting. Rather, a layering of various technologies can create a significant barrier to entry.

As those who seek to introduce counterfeit or adulterated products into the supply chain become more sophisticated, so, too, must the technologies that manufacturers, distributors and pharmacies employ to defeat them. Current and emerging technologies, such as those employing electronic product codes (EPC)/radio frequency identification (RFID), hold the most promise for tracking, tracing and authenticating a product's movement across the supply chain.

Using EPC/RFID technology, a tiny radio frequency chip containing essential data in the form of an electronic product code will allow supply chain stakeholders to track the chain of custody (or pedigree) of every unit of medication on an individual basis. By tying each unit to a unique electronic ID, products can be tracked electronically through the supply chain.

Tremendous progress is being made in the development and adoption of EPC/RFID technology in the pharmaceutical market. This is a monumental endeavor that requires close collaboration among all constituents of the healthcare supply chain. That is why HDMA will co-sponsor the second RFID Summit with the National Association of Chain Drug Stores to provide a forum for further education on the development and deployment of RFID technology. Moreover, many of our members are participating in pilot studies utilizing RFID tags on pharmaceutical products. These pilot activities of our members are helping us understand the challenges and opportunities of RFID as we work toward implementation on a broader scale on behalf of patient safety.

In our ongoing effort to assist the industry in moving toward EPC/RFID implementation, the HDMA Foundation launched a major research initiative in partnership with Rutgers University to study key issues surrounding data management and data sharing in healthcare, the key elements in advancing track and trace solutions. This is groundbreaking research that will define the business case and the safety benefits for data management and data sharing. This effort is a key component in HDMA's overall strategy to promote the industry-wide adoption of current and emerging new technologies. Phase I of the report is expected to be released by the end of 2006. Phase II of the study, which will provide a blueprint for how to most effectively share data across the supply chain, is in development now, and expected to be released in 2007.

As with any new technology, excitement can overshadow reality. Before widespread adoption of EPC/RFID can occur, business issues must first be resolved, standard real time systems have to be designed and trading partners have to integrate new technologies into current business practices and systems. Changes and processes of this magnitude involving new technology across a complex supply chain are monumental and take time to implement. Given the importance of maintaining a safe and reliable medicine supply, it is essential that this effort proceed forward in a close collaboration between the supply chain partners and government regulators.

In order for EPC/RFID to become a reality, a single, uniform approach is required. Current state-by-state pedigree requirements, however, are inconsistent and contradictory. These varying requirements divert human, technology and capital resources away from effective anti-counterfeiting solutions, and undercut efforts to systematically deploy EPC/RFID across the supply chain. Siphoning off resources to develop unproven, temporary systems in order to comply with individual state requirements is a step in the wrong direction. A uniform standard for pedigree requirements is necessary to prevent a patchwork of regulatory standards that take away from real solutions, such as EPC/RFID.

### *3. Alliances With Law Enforcement, Regulators and Trading Partners*

Each member of the supply chain – the manufacturer, the distributor and the pharmacy – must work in tandem to ensure a safe and reliable supply of prescription drugs for patients. To this end, HDMA, the National Association of Chain Drug Stores (NACDS) and the Pharmaceutical Research and Manufacturers of American (PhRMA), cosigned a March 2, 2006 letter to FDA Associate Commissioner for Policy and Planning Randall Lutter formally stating our commitment to join together to seek industry-wide solutions to advance patient safety, supply chain security and business efficiencies. Moving forward, we will continue to work with these and other allied groups to identify additional ways our members can work together to support a more secure medicine supply chain for pateint safety.

Separately, HDMA in 2005 joined FDA's Counterfeit Alert Network (CAN). The Counterfeit Alert Network informs consumers, pharmacists, healthcare professionals, distributors and others of counterfeit drug incidents, and provides education on ways to

identify and prevent counterfeits from entering the U.S. medicine supply. As a partner in the CAN, HDMA will distribute time-sensitive FDA messages and information on specific counterfeit incidents to member distribution companies. HDMA also will provide educational messages about counterfeit drugs, as well as information needed to recognize and report suspect or counterfeit drug products to FDA.

Most recently, HDMA in June 2006 joined a partnership of law enforcement and professional pharmacy organizations using RxPATROL®, an information clearinghouse designed to collect, analyze and share information on pharmacy robberies, burglaries and theft of controlled substances. RxPATROL (Pattern Analysis Tracking Robberies and Other Losses) is designed to help pharmacists guard against potential robberies and burglaries, and to assist law enforcement efforts to apprehend and prosecute pharmacy theft suspects. As part of the partnership, HDMA has implemented a process whereby its members can report incidents of any type of theft to RxPATROL. Additionally, all HDMA members will receive a security report - developed by RxPATROL using crime trend analyses and security/vulnerability assessments - offering guidance on how to minimize the risk of theft-related crime.

***4. Developing and Implementing Industry Best Practices***

Finally, the entire supply chain is constantly identifying new ways to improve upon business practices that can enhance product safety. HDMA has strongly recommended that manufacturers, distributors and pharmacies all implement best business practices to further protect the integrity of the pharmaceutical supply chain.

HDMA has recommended thorough security measures, which should be conducted before beginning any business relationship. At a minimum, supply chain partners should:

1. conduct civil and criminal background checks;
2. conduct site inspections;
3. conduct ongoing PDMA compliance reviews;
4. conduct licensure review;
5. maintain a list of "at risk" products; and
6. develop corporate systems to report suspicious or counterfeit products.

**Conclusion**

In conclusion, HDMA members recognize the public trust placed upon them to ensure that authentic pharmaceutical products are handled, stored and ultimately, dispensed to patients safely and efficiently. We have zero tolerance for criminals who counterfeit patient medicines, and we are committed to ongoing, multi-layered strategies that further secure the supply chain and protect patient safety. We will continue to work with the FDA, state regulatory authorities and supply chain partners to maintain our focus on the safe, secure and efficient delivery of healthcare products. Securing the nation's prescription drug supply chain requires constant vigilance in cooperation with all supply chain partners – from the manufacturer, to the distributor, to the pharmacy. A combination of many approaches is required, involving uniform licensure standards, tough regulation and consistent enforcement, the use of innovative new technologies and

the adoption of best business practices. The health and safety of our nation, literally, is at stake.

HDMA appreciates this opportunity to provide the perspective of the nation's primary, full-line, full-service healthcare distributors on these critically important issues and I would be pleased to answer any questions.

Mr. SOUDER. Thank you.

Our last witness today is Mr. Raber from Huntertown, IN. You are at the forefront of some of this technology, and I look forward to your testimony.

**STATEMENT OF RICK RABER**

Mr. RABER. Thank you Chairman Souder, Mr. Gutknecht and subcommittee members. It is a great honor to sit before you today.

From childhood it was ingrained in my life that Godly character was vital to success in life. Part of that character was to fulfill my civic responsibility. So I want to thank you today for the privilege of serving here today by testifying regarding the security in the pharmaceutical supply chain.

I am before you today as one with close to a decade of experience integrating radio frequency identification [RFID]. Our team at Northern Apex has utilized the technology in many areas in addition to pharmaceutical. We are an experienced stakeholder by virtue of the customers for whom we have integrated RFID onto their drugs. As project manager for Northern Apex, I led what many consider to be the world's first pharmaceutical production use of RFID. We worked with Purdue Pharma to place smart labels on produced popular pain medication Oxycontin.

The solution identified bottles on the production lines at speeds greater than two and a half bottles per second. Once packaged in the sealed tamper evident case, 48 individual bottles could be verified in less than 5 seconds. Since that initial project, I have been directly involved in designing several pharma implementations.

The discussion at hand regarding the security of the drug supply should not be about how bad the existing system is but rather ways for us to improve the already reliable process. The relative number of incidents to overall production of prescriptions is low but clearly increasing.

As we examine options which can be utilized to enhance the chain of custody, there are many things to consider. First, are there technologies that exist today which could bolster the security of drug supply? Second, are the technologies under consideration being used today? Finally, is there cause to implement further technologies?

Today millions of electronic transactions are being utilized around the world. They allow us to determine the chain of events related to a Web site visit or a trade on Wall Street. The FDA has already proposed using this technology in its prescription of an electronic or any pedigree.

This electronic transaction records the chain of custody for a drug and is a significant improvement over the paper pedigree of today. There are, however, additional technologies which could complement this electronic pedigree. Consider having the trackability based on a unique serial number being associated with every bottle, every case and every pallet. As each item is assembled into the next larger shipping unit, they are automatically associated, recorded through a data base and used to enhance the electronic pedigree. This is the basis of the RFID schemes presently being used by GlaxoSmithKlein on Trizivir, Pfizer on Viagra and Purdue on Oxycontin as well as others.

Complimentary technologies, such as 2-D barcodes, biometrics, telematatics and GPS could also be implemented at key spots in the supply chain. Technologies like RFID and others can change the effectiveness of the supply chain.

Ladies and gentlemen, these are not things from a Star Wars movie. As Mr. Gutknecht replied, they are real. This is an American version that exists and is being done.

The Department of Defense and Wal-Mart and others have mandated their suppliers use the technologies for incoming shipments to their receiving locations.

There are some obstacles to seeing rapid widespread adoption though. Within the Pharma and RFID industry, there is an ongoing debate over the modes and frequencies of RFID technology and its operation. There are data base, interface and privacy concerns. Even with these issues, industries have teamed together to successfully implement item level track-and-trace technology.

While some States have moved to implement pedigree legislation, these efforts have produced confusion on the parts of some of my friends sitting next to me today, drug manufacturers and distributors, in trying to accommodate just a few that exist today. Imagine 50 different ones.

For this committee to consider enhancing the present pedigree legislation to include a set of the described technologies in my opinion is prudent. Does the risk warrant the effort to change? There is no question that people's lives have been greatly affected by the issue at hand. The cost to some has been their life.

With the instances of breach which have already occurred, it is not out of the question to see this supply chain as a means for hostiles to suddenly attack the populous before even being discovered. In the same way some have misused the drugs created to help and heal, nefarious individuals will use and pervert the technologies and solutions we're even talking about today.

The enemies of the safe drug supply chain are clearly getting smarter. They are leveraging ever increasing technologies and levels beyond what we can imagine, and the good guys should pursue doing the same. The risk is growing and shouldn't be ignored.

Mr. Chairman and subcommittee members, again, thank you for the privilege of testifying here today, and I am open to any questions you might have.

[The prepared statement of Mr. Raber follows:]

101

Written Testimony

Of

Rick Raber

Northern Apex Corporation

Fort Wayne, Indiana

Presented on 11 July, 2006

before the

109th Congress of the United States

House of Representatives

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Committee on Government Reform

Chairman Souder, Members of the Subcommittee and Staff. It is with great pleasure and honor that I sit before you today. From childhood, it was ingrained into my life that Godly character was vital to success in life and that type of character was to include civic responsibility. So I want to humbly say Thank You, for the privilege of serving you here today and testifying concerning the matter of security within the pharmaceutical supply chain. I would ask at this time that you enter my provided written testimony into the record.

I come before you today as one with close to a decade of experience in the use and integration of Radio Frequency Identification, otherwise known as RFID. Our team at Northern Apex has utilized the technology in the areas of manufacturing, security, inspection and state government as well as pharmaceutical. Our organization has never received any federal funds for research or as a developer related to this technology or any other effort. We are an experienced stake holder by virtue of the customers for whom we have and will continue to work with concerning the use of RFID for tracing their drugs through the supply chain.

As RFID project manager for Northern Apex, I led what many consider the world's first pharmaceutical supply chain production use of RFID. We worked with Purdue Pharma L.P and other technology providers to implement a process which placed smart labels on Purdue's popular pain medication, Oxycontin. The solution was able to identify individual bottles on the production line at speeds of 150 bottles per minute. A sealed, tamper-evident case of 48 individual bottles could be verified in less than 5 seconds. Since that time, I have been directly involved in designing several pharma manufacturing implementations that are using RFID today in production.

These efforts have led to interactions with companies from many aspects of the pharmaceutical supply chain including label manufacturers, packagers, distributors, bottle handling equipment, drug manufacturers, as well as business intelligence software providers.

This experience has provided significant interaction with the processes a drug manufacturer is required to follow to in order to produce a drug that is FDA approved. The Code of Federal Regulations Title or Part 21 addresses at great length, good manufacturing processes, software validation and the overall accountability of the manufacturer to provide a safe, consistent, high quality product to the market.

The discussion at hand regarding the security of the pharmaceutical supply chain is not about how bad the existing process is but rather ways for us to improve an already reliable process when examined from a pure percentage standpoint. We have some of the best pharma manufacturers and distributors in the world within our borders and the relative number of incidents to overall production and prescriptions is low but clearly increasing. I cannot speak to the level or overall risk associated with counterfeiting, dilution, removal, modification and re-introduction, theft or other things which have occurred in the drug supply chain.

However, just by the fact that we are having this hearing, it is clear that there is reason to consider what happens to those drugs, once they leave the manufacturer and enter the distribution and wholesale chain.

While I'm not able to address the specific risk levels, I am qualified to speak concerning the technologies available to us, which when combined, could have a significant impact on the way trading is accomplished in the pharmaceutical industry.

As we examine options which could be utilized to influence the chain of custody of a controlled substance, there several things to consider. First, many technologies exist today which can further bolster the security of the drug supply.

Presently millions of electronic transactions are already being utilized in the world daily that allow us to ascertain the chain of events related to a website visit, a trade on Wall Street, along with hundreds of other everyday interactions. The FDA has already addressed using this type of technology in its description of an electronic or e-pedigree. This electronic transaction recording the chain of custody for a drug is a significant improvement over the paper pedigree of today.

The FDA's June 8, 2006 Counterfeit Drug Task Force report highlighted an important choice to no longer delay the cut-in date requirement of some existing pedigree requirements. This is a great initial move towards tightening the security of our drug supply chain.

There are however additional means that could complement the "traceable" transaction. These could be overt and covert. They could involve monitoring the Item, Case, Pallet and even Shipment Trailer level.

By using the group of technologies known as Auto-Identification, it is practical and real to consider having a track and trace unique serial number or ID associated with every bottle, case and pallet. As each lower level item is assembled into the next larger shipping unit, they would automatically be associated, recorded to a database and used to enhance the electronic pedigree. This is the basis of the RFID schemes presently being utilized by GlaxoSmithKline, Pfizer, Purdue Pharma and others.

It is also real to have the shipping company associate the trailer which contains a shipment, to their on board GPS and tele-matics systems to trace real time status of a controlled substance shipment. This is much like how you can trace today whether or not your UPS or FedEx package is out for delivery or has already been delivered. Many freight companies already have means for tracing their tractor-trailer rigs in real time using combined tele-matics and GPS technologies.

Other technologies such as 2-D barcodes and biometrics could also be implemented at key spots in the supply chain. Are all of these practical or necessary? That is yet to be determined by the extent to which we see the threat.

Secondly, many of these technologies are being implemented today by many different industries and organizations. The DOD has already seen the value of these Auto-ID technologies, utilizing them in battlefield logistics and has mandated their suppliers to begin using the technology for incoming shipments to their receiving locations.

We are not talking about technology that is light years away. In every instance that I've described, the different technologies exist today, which when combined, could provide a framework for an exponential improvement in the security of the drug supply chain.

Related to these technologies, there are some obstacles to the rapid widespread adoption. The RFID and Pharma industries have an ongoing debate over the value of certain modes and frequencies of RFID operation. There are clear reasons which begin to explain the debate but certainly only time and testing will provide true understanding. While I would not accuse the RFID manufacturers of any wrong doing, they are all clearly pushing their respective product to be the technology of choice for the industry. As a business' focused on success, it is in their best interest to see it become the standard. Pressing the adoption

of their specific technology, in effect creates a consumable, one-time use item. Item level serialization for each bottle of pills equals a lot of bottles that would require a tremendous number of smart labels. This process leads to innovation and healthy competition and is good for the RFID industry as well as those who use the technology.

Even with these uncertainties, the RFID and Pharma industries have combined to successfully implement item level track and trace using the two primary technologies. Pfizer tracks Viagra with item level tags of the High Frequency (HF) type and Ultra High Frequency (UHF) case tags. GlaxoSmithKline uses the same mix of item level and case level RFID technologies. Purdue Pharma has implemented the technology using item level tags of the UHF type. At this time, either technology is capable of providing schemes for traceability.

As you would expect, there are plusses and minuses to each. It's my belief that this body should not involve itself with that level of discussion. It would be the equivalent of deciding VHS versus Beta some twenty years ago.

However, with a vision towards broader adaptation, this body might consider whether or not further federal regulations should mandate the extent, description and complexity of the electronic drug pedigree track and trace efforts.

While there has been a level of adoption by certain states of the pedigree concept, there are clearly different opinions of how that pedigree should be manifested from Florida to California to Indiana. This leads to confusion on the part of both the distributors and the drug manufacturers as to how the pedigree should be accomplished. Leaving the core manifestation to the states could result in 50 different ways that a manufacturer has to provide their pedigree information. The FDA has provided excellent leadership and put a

significant amount of work and effort into annual reports, conferences with industry representatives and the overall education related to these concerns. Other organizations, like ePC Global, have health and life science action groups consisting of drug manufacturers, distributors, technology providers and integrators who are also attempting to answer these questions.

Do the FDA and Congress wait for the industry to gradually adopt ever increasing technologies? Much like the Wal-Mart RFID initiative for their top suppliers to incorporate case and pallet level RFID, its widespread adoption probably won't occur until the line in the sand is drawn by either the FDA or some form of legislation.

The June 2006 FDA report mentioned earlier does an excellent job detailing other concerns related to the broad adoption of the RFID component. These include database items, privacy concerns, labeling information and the like. While these are all items to be addressed, they should be viewed as hurdles in a race rather than obstacles that can't be overcome.

As part of the Committee on Government Reform, you are keenly aware that there is always a cost to change. The question is whether or not the risk and return make it valuable. There is not a quick easy answer to this question. Still, one factor that should minimize the overall cost of traceability is the reality that there are companies world wide, both inside and outside the pharma space, who use RFID and other auto identification schemes every day in their business. That number is constantly growing. Does the risk warrant the effort? There is no question that people's lives have been greatly affected by the issue at hand. Cancer, HIV patients and others have been the

victims of selfish, greedy people who would compromise their integrity for financial gain. The cost to some has been their life.

We know that some foreign and domestic counterfeiters have created the fine art of turning gypsum or the equivalent of drywall dust into tablets which look so much like the real medication that you have to analyze them to be sure. What keeps someone from introducing a poison instead of gypsum?

With the instances of breach which have already occurred, it is not out of the question to see the Pharmaceutical Supply Chain as a means for hostiles, whether foreign or domestic, to subtly attack the populace before being discovered.

We have addressed anthrax, small pox and other biological items through the development and advancement of drugs like Cipro. Yet the supply chain for the drugs used everyday could be susceptible to introduction of similar bioterrorism schemes. It is for good reason that the recent FDA report recommends that the countermeasure drug chain begin using these technologies.

The US is not alone. This is a global issue. Similar counterfeiting activities are happening world wide. With the onset of the internet pharmacy, people worldwide are at risk. Although many informed people don't purchase their medications in this manner, the sheer presence of this market provides a means for the propagation of such medical counterfeits.

To what level should we intervene is for you to determine. In general, I am not an advocate of the federal government creating more laws, which require more people to enforce them and result in greater costs to the end user. However, there are ways we can put controls in place which leverage technologies of the day. It could radically improve

over the present system and further minimize the risk, without adding exorbitant cost to the product. Savings could be realized in areas other than the intended or obvious.

Are Radio Frequency Identification and other technologies the end all to fix this issue? Surely not! Deception, greed and evil have been around since the Garden of Eden. I believe it will continue until the end of the civilization as we know it.

In the same way some have misused the drugs created to help and heal; other nefarious individuals will use and pervert the technologies and solutions we are discussing today. The enemies of a safe drug supply chain, whether greed or hostility based, are clearly getting smarter. They are leveraging ever increasing levels of technology and the good guys should pursue doing the same.

In summary, the existing US drug supply chain is the best in the world and has been very successful. While it is the best, there are technologies that offer opportunities for greater security in the supply chain that would benefit the customer and the industry. There will continue to be changes in the current technologies that are available today, but this should not impede making advances today with vision for how technology of the future could also enhance the process. Finally, there is a clear risk to the drug supply from both a hostile and a greed based criminal. This risk is growing and shouldn't be ignored.

Mr. Chairman, and Subcommittee members, again Thank you for the privilege of testifying here today. I am open to questions that you may have.

110

Written Testimony

Of

Rick Raber

Northern Apex Corporation

Fort Wayne, Indiana

Presented on 11 July, 2006

before the

109th Congress of the United States

House of Representatives

Subcommittee on Criminal Justice, Drug Policy and Human Resources

Committee on Government Reform

Chairman Souder, Members of the Subcommittee and Staff. It is with great pleasure and honor that I sit before you today. From childhood, it was ingrained into my life that Godly character was vital to success in life and that type of character was to include civic responsibility. So I want to humbly say Thank You, for the privilege of serving you here today and testifying concerning the matter of security within the pharmaceutical supply chain. I would ask at this time that you enter my provided written testimony into the record.

I come before you today as one with close to a decade of experience in the use and integration of Radio Frequency Identification, otherwise known as RFID. Our team at Northern Apex has utilized the technology in the areas of manufacturing, security, inspection and state government as well as pharmaceutical. Our organization has never received any federal funds for research or as a developer related to this technology or any other effort. We are an experienced stake holder by virtue of the customers for whom we have and will continue to work with concerning the use of RFID for tracing their drugs through the supply chain.

As RFID project manager for Northern Apex, I led what many consider the world's first pharmaceutical supply chain production use of RFID. We worked with Purdue Pharma L.P and other technology providers to implement a process which placed smart labels on Purdue's popular pain medication, Oxycontin. The solution was able to identify individual bottles on the production line at speeds of 150 bottles per minute. A sealed, tamper-evident case of 48 individual bottles could be verified in less than 5 seconds. Since that time, I have been directly involved in designing several pharma manufacturing implementations that are using RFID today in production.

These efforts have led to interactions with companies from many aspects of the pharmaceutical supply chain including label manufacturers, packagers, distributors, bottle handling equipment, drug manufacturers, as well as business intelligence software providers.

This experience has provided significant interaction with the processes a drug manufacturer is required to follow to in order to produce a drug that is FDA approved. The Code of Federal Regulations Title or Part 21 addresses at great length, good manufacturing processes, software validation and the overall accountability of the manufacturer to provide a safe, consistent, high quality product to the market.

The discussion at hand regarding the security of the pharmaceutical supply chain is not about how bad the existing process is but rather ways for us to improve an already reliable process when examined from a pure percentage standpoint. We have some of the best pharma manufacturers and distributors in the world within our borders and the relative number of incidents to overall production and prescriptions is low but clearly increasing. I cannot speak to the level or overall risk associated with counterfeiting, dilution, removal, modification and re-introduction, theft or other things which have occurred in the drug supply chain.

However, just by the fact that we are having this hearing, it is clear that there is reason to consider what happens to those drugs, once they leave the manufacturer and enter the distribution and wholesale chain.

While I'm not able to address the specific risk levels, I am qualified to speak concerning the technologies available to us, which when combined, could have a significant impact on the way trading is accomplished in the pharmaceutical industry.

As we examine options which could be utilized to influence the chain of custody of a controlled substance, there several things to consider. First, many technologies exist today which can further bolster the security of the drug supply.

Presently millions of electronic transactions are already being utilized in the world daily that allow us to ascertain the chain of events related to a website visit, a trade on Wall Street, along with hundreds of other everyday interactions. The FDA has already addressed using this type of technology in its description of an electronic or e-pedigree. This electronic transaction recording the chain of custody for a drug is a significant improvement over the paper pedigree of today.

The FDA's June 8, 2006 Counterfeit Drug Task Force report highlighted an important choice to no longer delay the cut-in date requirement of some existing pedigree requirements. This is a great initial move towards tightening the security of our drug supply chain.

There are however additional means that could complement the "traceable" transaction. These could be overt and covert. They could involve monitoring the Item, Case, Pallet and even Shipment Trailer level.

By using the group of technologies known as Auto-Identification, it is practical and real to consider having a track and trace unique serial number or ID associated with every bottle, case and pallet. As each lower level item is assembled into the next larger shipping unit, they would automatically be associated, recorded to a database and used to enhance the electronic pedigree. This is the basis of the RFID schemes presently being utilized by GlaxoSmithKline, Pfizer, Purdue Pharma and others.

It is also real to have the shipping company associate the trailer which contains a shipment, to their on board GPS and tele-matics systems to trace real time status of a controlled substance shipment. This is much like how you can trace today whether or not your UPS or FedEx package is out for delivery or has already been delivered. Many freight companies already have means for tracing their tractor-trailer rigs in real time using combined tele-matics and GPS technologies.

Other technologies such as 2-D barcodes and biometrics could also be implemented at key spots in the supply chain. Are all of these practical or necessary? That is yet to be determined by the extent to which we see the threat.

Secondly, many of these technologies are being implemented today by many different industries and organizations. The DOD has already seen the value of these Auto-ID technologies, utilizing them in battlefield logistics and has mandated their suppliers to begin using the technology for incoming shipments to their receiving locations.

We are not talking about technology that is light years away. In every instance that I've described, the different technologies exist today, which when combined, could provide a framework for an exponential improvement in the security of the drug supply chain.

Related to these technologies, there are some obstacles to the rapid widespread adoption. The RFID and Pharma industries have an ongoing debate over the value of certain modes and frequencies of RFID operation. There are clear reasons which begin to explain the debate but certainly only time and testing will provide true understanding. While I would not accuse the RFID manufacturers of any wrong doing, they are all clearly pushing their respective product to be the technology of choice for the industry. As a business' focused on success, it is in their best interest to see it become the standard. Pressing the adoption

of their specific technology, in effect creates a consumable, one-time use item. Item level serialization for each bottle of pills equals a lot of bottles that would require a tremendous number of smart labels. This process leads to innovation and healthy competition and is good for the RFID industry as well as those who use the technology.

Even with these uncertainties, the RFID and Pharma industries have combined to successfully implement item level track and trace using the two primary technologies. Pfizer tracks Viagra with item level tags of the High Frequency (HF) type and Ultra High Frequency (UHF) case tags. GlaxoSmithKline uses the same mix of item level and case level RFID technologies. Purdue Pharma has implemented the technology using item level tags of the UHF type. At this time, either technology is capable of providing schemes for traceability.

As you would expect, there are plusses and minuses to each. It's my belief that this body should not involve itself with that level of discussion. It would be the equivalent of deciding VHS versus Beta some twenty years ago.

However, with a vision towards broader adaptation, this body might consider whether or not further federal regulations should mandate the extent, description and complexity of the electronic drug pedigree track and trace efforts.

While there has been a level of adoption by certain states of the pedigree concept, there are clearly different opinions of how that pedigree should be manifested from Florida to California to Indiana. This leads to confusion on the part of both the distributors and the drug manufacturers as to how the pedigree should be accomplished. Leaving the core manifestation to the states could result in 50 different ways that a manufacturer has to provide their pedigree information. The FDA has provided excellent leadership and put a

significant amount of work and effort into annual reports, conferences with industry representatives and the overall education related to these concerns. Other organizations, like ePC Global, have health and life science action groups consisting of drug manufacturers, distributors, technology providers and integrators who are also attempting to answer these questions.

Do the FDA and Congress wait for the industry to gradually adopt ever increasing technologies? Much like the Wal-Mart RFID initiative for their top suppliers to incorporate case and pallet level RFID, its widespread adoption probably won't occur until the line in the sand is drawn by either the FDA or some form of legislation.

The June 2006 FDA report mentioned earlier does an excellent job detailing other concerns related to the broad adoption of the RFID component. These include database items, privacy concerns, labeling information and the like. While these are all items to be addressed, they should be viewed as hurdles in a race rather than obstacles that can't be overcome.

As part of the Committee on Government Reform, you are keenly aware that there is always a cost to change. The question is whether or not the risk and return make it valuable. There is not a quick easy answer to this question. Still, one factor that should minimize the overall cost of traceability is the reality that there are companies world wide, both inside and outside the pharma space, who use RFID and other auto identification schemes every day in their business. That number is constantly growing. Does the risk warrant the effort? There is no question that people's lives have been greatly affected by the issue at hand. Cancer, HIV patients and others have been the

victims of selfish, greedy people who would compromise their integrity for financial gain. The cost to some has been their life.

We know that some foreign and domestic counterfeiters have created the fine art of turning gypsum or the equivalent of drywall dust into tablets which look so much like the real medication that you have to analyze them to be sure. What keeps someone from introducing a poison instead of gypsum?

With the instances of breach which have already occurred, it is not out of the question to see the Pharmaceutical Supply Chain as a means for hostiles, whether foreign or domestic, to subtly attack the populace before being discovered.

We have addressed anthrax, small pox and other biological items through the development and advancement of drugs like Cipro. Yet the supply chain for the drugs used everyday could be susceptible to introduction of similar bioterrorism schemes. It is for good reason that the recent FDA report recommends that the countermeasure drug chain begin using these technologies.

The US is not alone. This is a global issue. Similar counterfeiting activities are happening world wide. With the onset of the internet pharmacy, people worldwide are at risk. Although many informed people don't purchase their medications in this manner, the sheer presence of this market provides a means for the propagation of such medical counterfeits.

To what level should we intervene is for you to determine. In general, I am not an advocate of the federal government creating more laws, which require more people to enforce them and result in greater costs to the end user. However, there are ways we can put controls in place which leverage technologies of the day. It could radically improve

over the present system and further minimize the risk, without adding exorbitant cost to the product. Savings could be realized in areas other than the intended or obvious.

Are Radio Frequency Identification and other technologies the end all to fix this issue? Surely not! Deception, greed and evil have been around since the Garden of Eden. I believe it will continue until the end of the civilization as we know it.

In the same way some have misused the drugs created to help and heal; other nefarious individuals will use and pervert the technologies and solutions we are discussing today. The enemies of a safe drug supply chain, whether greed or hostility based, are clearly getting smarter. They are leveraging ever increasing levels of technology and the good guys should pursue doing the same.

In summary, the existing US drug supply chain is the best in the world and has been very successful. While it is the best, there are technologies that offer opportunities for greater security in the supply chain that would benefit the customer and the industry. There will continue to be changes in the current technologies that are available today, but this should not impede making advances today with vision for how technology of the future could also enhance the process. Finally, there is a clear risk to the drug supply from both a hostile and a greed based criminal. This risk is growing and shouldn't be ignored.

Mr. Chairman, and Subcommittee members, again Thank you for the privilege of testifying here today. I am open to questions that you may have.

**Appendix A – FDA Testimony – July 11, 2006**

## Efforts of FDA's Office of Criminal Investigations (OCI)

FDA believes that the most important factor in preventing counterfeit drugs from reaching American consumers is protection of the nation's drug supply chain. A closed, secure distribution system deters illicit diversion and makes it more difficult for counterfeiters and other unscrupulous actors to introduce their dangerous products into the wholesale supply chain. OCI focuses a significant part of its enforcement efforts on investigations of illicit diverters and others who threaten the integrity of the drug supply chain. These enforcement efforts against illicit diverters have resulted in detection and dismantling of counterfeit schemes.

Below are examples of significant counterfeit drug cases that were closed in the past year:

**Counterfeit Lipitor**
Last year, three businesses and eleven individuals were indicted for their involvement in a $42 million dollar conspiracy to sell counterfeit, smuggled, and misbranded Lipitor and other drugs and for participating in a conspiracy to sell stolen drugs. To date the case has resulted in nine convictions, $2.8 million in forfeitures, and 12 others are under indictment awaiting trial, as well as $10,000,000 more in alleged proceeds to be forfeited. On June 30, 2006, one of the defendants was sentenced to nine years and six months in Federal prison and ordered to pay $1,806,905 in restitution to Pfizer, Inc.

**16 People Arrested in $200 Million Drug Diversion Scheme**
This joint OCI-multi agency investigation resulted in the September 21, 2005, arrests of 16 defendants based on charges in a 201 count Federal indictment related to a scheme to divert more than $200 million in fraudulently obtained pharmaceuticals.

**Convictions in Illegal Blood Derivative Diversion Scheme**
On March 29, 2006, two owners of a Florida pharmaceutical wholesale distributor were convicted of more than 247 criminal counts as the result of an extensive OCI investigation of an illegal medical products diversion scheme, which defrauded the Medicaid and Medicare programs of more than $45,000,000. The criminal counts included wire fraud, money laundering, conspiracy, and racketeering.

**Nationwide Drug Diversion Investigation**
In this still ongoing investigation, six individuals and six businesses in New York, Utah, New Jersey and California, were charged in a ten-count indictment with mail fraud and the unauthorized distribution of prescription drugs without pedigrees in connection with a major drug diversion operation. With the assistance of other Federal and state law enforcement agencies, OCI uncovered a scheme where several secondary wholesalers bought, sold and distributed drugs. To date, two individuals and two businesses have pled guilty to charges related to the failure to provide drug pedigrees as required under the Prescription Drug Marketing Act, money laundering and mail fraud.

**Appendix A – FDA Testimony – July 11, 2006**

**Texas Pharmacist Convicted on Counterfeit Drug Charges**
This joint OCI and U.S. Immigration and Customs Enforcement (ICE) case was initiated following the seizure of a package mailed from China containing several thousand counterfeit Viagra and Cialis tablets. On May 24, 2006, the pharmacist was convicted of conspiracy and counterfeit drug charges and is awaiting sentencing.

**Kentucky Pharmacist Pleads Guilty to Illegally Selling Prescription Drug Samples and Agrees to Pay $10.5 MILLION**
OCI uncovered a conspiracy involving a pharmacy owner in Kentucky who, along with others, obtained drug samples, repackaged them, and illegally sold them to the public.

**California Man Arrested on Counterfeit Drug Charges**
A California man was arrested on June 12, 2006, following an OCI investigation into the distribution of counterfeit drugs that he purchased from a Chinese supplier over the Internet.

**Counterfeit Lipitor, Viagra, and Cialis**
OCI and ICE conducted a joint investigation and assisted the Chinese authorities in determining the source of counterfeit drugs. As a result of this collaborative effort, Chinese authorities arrested 11 individuals who will be prosecuted by the Chinese government for their involvement in manufacturing and distributing counterfeit Lipitor, Viagra, and Cialis.

**Counterfeit Risperdal and Zyprexa**
Last year, one individual was sentenced to 30 months in jail for counterfeiting Zyprexa and Risperdal prescription labels and selling them to various individuals. A second individual was sentenced to 24 months in jail for the illegal wholesale distribution of prescription drugs and possession with the intent to distribute controlled substances.

**Appendix A – FDA Testimony – July 11, 2006**

## Efforts of FDA's Office of Criminal Investigations (OCI)

FDA believes that the most important factor in preventing counterfeit drugs from reaching American consumers is protection of the nation's drug supply chain. A closed, secure distribution system deters illicit diversion and makes it more difficult for counterfeiters and other unscrupulous actors to introduce their dangerous products into the wholesale supply chain. OCI focuses a significant part of its enforcement efforts on investigations of illicit diverters and others who threaten the integrity of the drug supply chain. These enforcement efforts against illicit diverters have resulted in detection and dismantling of counterfeit schemes.

Below are examples of significant counterfeit drug cases that were closed in the past year:

**Counterfeit Lipitor**
Last year, three businesses and eleven individuals were indicted for their involvement in a $42 million dollar conspiracy to sell counterfeit, smuggled, and misbranded Lipitor and other drugs and for participating in a conspiracy to sell stolen drugs. To date the case has resulted in nine convictions, $2.8 million in forfeitures, and 12 others are under indictment awaiting trial, as well as $10,000,000 more in alleged proceeds to be forfeited. On June 30, 2006, one of the defendants was sentenced to nine years and six months in Federal prison and ordered to pay $1,806,905 in restitution to Pfizer, Inc.

**16 People Arrested in $200 Million Drug Diversion Scheme**
This joint OCI-multi agency investigation resulted in the September 21, 2005, arrests of 16 defendants based on charges in a 201 count Federal indictment related to a scheme to divert more than $200 million in fraudulently obtained pharmaceuticals.

**Convictions in Illegal Blood Derivative Diversion Scheme**
On March 29, 2006, two owners of a Florida pharmaceutical wholesale distributor were convicted of more than 247 criminal counts as the result of an extensive OCI investigation of an illegal medical products diversion scheme, which defrauded the Medicaid and Medicare programs of more than $45,000,000. The criminal counts included wire fraud, money laundering, conspiracy, and racketeering.

**Nationwide Drug Diversion Investigation**
In this still ongoing investigation, six individuals and six businesses in New York, Utah, New Jersey and California, were charged in a ten-count indictment with mail fraud and the unauthorized distribution of prescription drugs without pedigrees in connection with a major drug diversion operation. With the assistance of other Federal and state law enforcement agencies, OCI uncovered a scheme where several secondary wholesalers bought, sold and distributed drugs. To date, two individuals and two businesses have pled guilty to charges related to the failure to provide drug pedigrees as required under the Prescription Drug Marketing Act, money laundering and mail fraud.

**Appendix A – FDA Testimony – July 11, 2006**

**Texas Pharmacist Convicted on Counterfeit Drug Charges**
This joint OCI and U.S. Immigration and Customs Enforcement (ICE) case was initiated following the seizure of a package mailed from China containing several thousand counterfeit Viagra and Cialis tablets. On May 24, 2006, the pharmacist was convicted of conspiracy and counterfeit drug charges and is awaiting sentencing.

**Kentucky Pharmacist Pleads Guilty to Illegally Selling Prescription Drug Samples and Agrees to Pay $10.5 MILLION**
OCI uncovered a conspiracy involving a pharmacy owner in Kentucky who, along with others, obtained drug samples, repackaged them, and illegally sold them to the public.

**California Man Arrested on Counterfeit Drug Charges**
A California man was arrested on June 12, 2006, following an OCI investigation into the distribution of counterfeit drugs that he purchased from a Chinese supplier over the Internet.

**Counterfeit Lipitor, Viagra, and Cialis**
OCI and ICE conducted a joint investigation and assisted the Chinese authorities in determining the source of counterfeit drugs. As a result of this collaborative effort, Chinese authorities arrested 11 individuals who will be prosecuted by the Chinese government for their involvement in manufacturing and distributing counterfeit Lipitor, Viagra, and Cialis.

**Counterfeit Risperdal and Zyprexa**
Last year, one individual was sentenced to 30 months in jail for counterfeiting Zyprexa and Risperdal prescription labels and selling them to various individuals. A second individual was sentenced to 24 months in jail for the illegal wholesale distribution of prescription drugs and possession with the intent to distribute controlled substances.

Mr. SOUDER. I thank you.

Let me start with you Mr. Raber and try to startup in the questioning.

We heard several witnesses say we need some sort of a uniform approach to this. As you've worked with this product and you've just alluded to the fact that it's very confusing, could you kind of explain what that means? Does it mean you have different readers, different frequencies? What is a practical—helping me and others understand what is necessary.

Mr. RABER. Within the RFID industry, sir, there are several different primary technologies. Without getting really, really technical here before you, there are two primary that are existing today. An HF at 13.56 megahertz and UHF in 868 to 915 megahertz. There is clearly a part of the technology sector that are trying to advance their technologies, and for good reasons. And I believe it is a good competitive factor. And otherwise, there are things related to what kind of products that some of the technologies have been able to be used on in the past. How does one of the technologies perform in a case, environment where you have 100 cases of Oxycontin a pallet? Are you able to read all 100 cases while they are there? And short range versus long range, there are clearly instances where short range is more desirable so that singulation is not an issue. If I have all these bottles sitting on a desk here today and I have certain versions of 900 megahertz technology, I could see that they would all be present here. However, I could not tell you which one was present before each witness here today depending on how that technology is utilized. So, therefore, some of the near-field communications and some of the things that are related to short-range technologies can present some desirable things.

Clearly the chain of custody and the way that electronic transaction occurs, RFID is a subset of that. It allows it to tie in better as has already been said multiple times today. How that transaction occurs certainly can take place without RFID ever playing a component in it.

What RFID does is allow us to scan bottles as they are going down the line, scan them as they are put into a multipack of 12 and shrink wrapped, scan them again as they are put into a tamper evident case of 48, scan them again as they go into a vault, scan them again as they are received at a health care distributor, scan them again as they are shipped out to another wholesaler. Those kinds of things.

RFID and other technologies could significantly change the way that looks. But the technologies themselves, they are real. They are working today. They will continue to advance, but to hold off and say that the RFID technology will be adopted by, as Mr. Gutknecht implied, that there will be people that may avoid doing it until they are made to do it. It was the same way that has happened with the Wal-Mart mandate. Wal-Mart several years ago initiated that their top 100 suppliers from a dollar perspective start shipping in case level, scanning them, and pallet level. Many of those people didn't do it until the deadline showed right up.

I think the health care distributors really have seen value though when, as you talked about, 16 percent, if they are able to close the security of the supply chain and eliminate some of the

counterfeit, there actually can be a very legitimate case made for the value coming back to them in increased sales because their products are really truly making it to the field rather than otherwise. So, hopefully, I have answered your question there related to some of the mix up about what the technologies are.

Mr. SOUDER. When I visited your facility and you talked some about the Wal-Mart, didn't you say they also have the ability to take it down to the very individual bottle? And could you describe two things with that, and I also remember that part of their reason was internal theft. It wasn't just counterfeiting. In other words, you can figure out who's stealing things. And if you want to comment on those two things and then leading to this question: What are the functional approximate, without giving out competitive things and so on, approximate cost questions that were involved in here in the different types of frequencies, the difference between the pallet and an individual, the ability, are people going to have to get scanners that are specialized with this?

Mr. RABER. Sure. First of all, item level tracking and unique serial number that would be addressed to each individual bottle that would go through the distribution chain, that is very real, very practical. It does happen today. Several hundred thousand bottles of Oxycontin have been tracked. Many bottles of Pfizer's Viagra and GlazoSmithKline's Trizivir have all been tagged in large lots.

The bottles are individually being tracked, we can tell, prior to the shipping of the case and prior to leaving the facility that those drugs are there, that there really are 48 in the box, that the 48 have moved through the supply chain. That can occur.

So item level really does happen. What that looks like on the different kinds of things, whether that's a liquid medication in a vile or whether that's a dosage medication that is in a capsule or something; whether it's in a blister pack or the different types of things that may occur. Those all play into the manifestation of what technology you would use at item level to be able to track that technology, to track that item.

So are there technologies that exist today? As the gentleman from the HDMA said here, not one technology, whether UHF or HF is going to be the answer to the world, universe and everything as we know it in tracking pharmaceutical items, the value associated with that, the supply and demand has clearly driven the cost of an RFID tag down. We have seen in our 10-plus, 10 years experience of watching tags that used to be in the double digits and closer to $1 to now being down in volume below 30 cents regularly and in high volumes certainly below that. And so there are people that are claiming sub 10 cents now in volume. And when we are talking volume, we are talking about millions and hundreds of millions of tags a year where somebody would commit to.

Those we are yet to see in production, and I will clarify my statement in that. We have yet to see in high volume production the single 3 or 4 cent tag in being delivered in volumes that would require to support the supply chain. That is another component that is not to be ignored.

The technology providers today, while the technologies do exist, Mr. Gutknecht, one of the things that clearly is an issue and they are all ramping up their ability to deliver this product, but there

has been a clear on the part of multiple organizations, the ability to get the product is something that should not be ignored. In order to tag, just picture Oxycontin alone or Viagra alone or some of the other drugs, Lipitor, those drugs and the amount of tags that it would take to support those kind of implementations are not negligible. They are significant. So that is something that the RFID manufacturers are required to do.

As it relates to the value related to the readers and the infrastructure that is put in place, many things have rapidly changed in the last 2 or 3 years since we first worked with simple technologies to do, Matrix and simple technologies to do the Purdue Oxycontin implementation and the technology is rapidly changing and working well.

Mr. SOUDER. Mr. Gutknecht.

Mr. GUTKNECHT. Mr. Chairman, and to this panel, thank you for coming. I think you all provided very excellent testimony.

Mr. Catizone, we have seen you at a number of these types of meetings, and I want to thank you for coming.

First of all, I want to make it clear that I really appreciate what the pharmacists do every day. I know they have a tough job. Frankly, what I have felt for a long time is, and this may sound funny, but I don't want people to buy their drugs over the Internet.

What I really want to do is create a system whereby our pharmacists have a little more freedom where they can buy their products from because American pharmacists are actually held hostage as well. And one of the arguments has been—and, Ms. Winckler, I am going to come to you because you said something so powerful and so true—we many times talk here in Washington particularly in terms of statistics and numbers and dollars and so forth. But at the end of all of this are real people with real faces. And I have a chance to meet a lot of these people with real faces. And this goes back a few years, and I understand we have probably gone beyond that, but I think the best example is the drug tamoxifen which is taken by women of all ages, but principally it is an anti-breast-cancer drug. That drug, a number of years ago when we began to do this research, you could buy in the United States for roughly $400 a month. You could buy it in Canada for $89. It was exactly the same drug made by the same company in the same plants. It was FDA approved. And yet for a lot of these people, if you have insurance, it's not that big of a deal, $400 versus $89. But believe it or not, there are a lot Americans who either don't have adequate insurance or whatever, but either way, I mean, I cannot defend the difference between $400 and $89 for the same drug. And this is why I am so frustrated because our own FDA and the pharmaceutical industry, when we began talking to them years ago about the technologies Mr. Raber talked about, their argument was, no, no, we can't do that.

What do you think? Can we do this?

Ms. WINCKLER. The first thing we have to do is move beyond that "we can't" and let's figure out how we can and what are those most cost-effective steps. So I think we can if we have enough consistency and uniformity to make it work, which I think is key particularly in the pedigree area, and then let's make sure as we are looking at identifying technologies, what is counterfeit proof today

may not be counterfeit proof tomorrow. So do we start—as you recommended, let's start small and start with a piece but then build into the system and understanding that we need to continually advance those technologies and move forward that we won't be able to be say—we will solve the counterfeit problem by continuing to work to stay ahead of the counterfeiters.

So I think we can but it does take that commitment and being able to listen and work with everyone and giving the regulators not only the authority but the resources to enforce and that is I think something that is a key role for everyone in this room to understand, that if we put a new penalty in or put a new requirement out there, it is well funded, and we do have the back up to make sure that it's enforceable.

Mr. GUTKNECHT. Well, we are more than willing to let the industry lead on this. I don't hold myself out as an expert on this technology. But we have some people in this town who are experts. I do agree with you. I mean, we have had to revisit the $20 bill several times in the last several years to try to come up with more sophisticated technologies to prevent the counterfeit of the $20 bill.

So success leaves clues, and are you ever going to prevent counterfeiting? Probably not. But we can make it extremely difficult and more complicated and more expensive to do that. And so success leaves clues, and they are all around us. The same company that makes the ink for this $20 bill makes the ink for this packaging, OK. And you can make it so it is very, very difficult for a low-cost supplier whether they are in India or China or Bangladesh, it doesn't matter. We can make it very complicated for them to counterfeit this packaging.

And these chips, one of the arguments we heard a few years ago when I first started talking about this technology, oh, they said, that's way too expensive. Mr. Raber, how would you respond to that? Is this way too expensive?

Mr. RABER. Value is always in the eyes of the beholder, sir. But, clearly, there are things that are happening. It is clearly that value is always in the eyes of the beholder. And the way that any individual market space or company addresses value is based on their response to that, but what we have seen over and over and over and a gentleman that I spoke with from Hewlett-Packard about a year ago spoke about the hidden value that occurs when you implement RFID technologies, there are clearly discussions that happen as it relates to not just the chain of custody and being able to close that more secure, but the way that you increase your accuracy of your supply chain so that your inventory is more accurate; the way that you reduce the amount of time and handling that it takes to occur—handling that it takes to handle 100 cases of a drug, the amount of time that it takes to create a paper pedigree. That value is clearly one that is not to be ignored.

Mr. GUTKNECHT. Well, I agree with that. Finally, let me say, Mr. Chairman, I have been in this thing for so long now that I just really suspect that there are people who have ulterior motives. OK. This is much less about consumer safety than it is the bottom line profit. Because once you have a system that is far more secure, all of the sudden the biggest argument that we have heard about not allowing pharmacists and consumers access to world class drugs at

world market prices, all of a sudden it changes the arithmetic about what Americans can and should pay.

I believe we ought to pay our fair share. The truth of the matter is I think we are a blessed country and we ought to be willing to pay and subsidize drugs in undeveloped countries. I think we ought to pay more than the people in sub-Saharan Africa, but I do not believe that American consumers should be required to subsidize the starving Swiss. I mean, it is time that we create what we have in virtually every other product class that is a world market. And I believe RFID and other off-the-shelf technologies can go a long way. Can we ever create a perfect system? No. But if we created a system where you had a better assuredness that these were in fact the products that the pharmacists carry that really are what they say they are, all of a sudden you create a marketplace that is much fairer for American consumers. This has huge implications. I want a safe drug supply. I don't want people buying drugs over the Internet. But as long as you have a system where Tamoxifin is $400 in the United States, and it's $89 in most of the industrialized world, this problem is going to get worse and worse and worse. And what we have encountered from the FDA so far is little more than food dragging.

If anybody wants to respond to that, you are more than welcome.

Ms. WINCKLER. If I could offer one suggestion as we look at this, at how to continue to move forward, it is to also consider that some of these anti-counterfeiting initiatives have benefits outside of the direct anti-counterfeiting question. Going unit-of-use packaging for example helps us on the part of my job that I want to spend my time on which is helping patients use their drugs correctly. It helps immensely with patient compliance, and so you have all these other areas where you can see a benefit. I think we have to look at our interventions and say, there is an anti-counterfeiting benefit; what other benefits do we see? What other impact does it have? And understand that what we do here not only affects the legitimate source of the drug supply but affects the medication supply generally for patients and worldwide as well.

Mr. CATIZONE. Congressman, the States are saying they can no longer wait. Florida, California have put in electronic pedigree requirements, and they are holding fast to those deadlines, 2006 and 2007. HDMA and the primary full service wholesalers are supporting those efforts, but there is a significant contingent of people that don't want this track-and-trace technology in place, are fighting it, are using every political trick they can in those States to defeat those implementation deadlines and working against any regulation and any tracking of those drugs. And so that is a significant battle that we need your support and need your help with because the States can't wait any longer.

Mr. GUTKNECHT. Let me just say that I know those tricks, and I know who those people are, and we do have a bill. Now it is not perfect, and we would love your input, but mostly, we would love your support. It is a little bill we put together. I am not an expert. Mr. Raber, people like you are, and we are willing to listen to you because we get so little help from our own agencies. But I would encourage you to at least look at H.R. 4829 and see if maybe we can't get something going, because I agree with you. Ultimately, we

are going to wind up with 50 different regulations, and this is one that is not just—I think this issue is a national issue, and it is an international issue. And I am not necessarily critical of California or any other State that wants to move forward with this, but I think it is an indication of just how slow we have been to respond to what is happening out there in the marketplace. So, again, thank you to the chairman, and the bells are going off, but I want to thank you for coming today and for your testimony.

Mr. SOUDER. Mr. Cummings.

Mr. CUMMINGS. Mr. Chairman, I only have a question or two.

Ms. Winckler, let me ask you this, do generic drugs present any unique situation different than what we would normally see with regard to these issues?

Ms. WINCKLER. It is probably fair to say that, because generic medications are generally lower cost, that they are less likely to be counterfeited. But I think there is still the risk of counterfeiting, and certainly as we look to trying to address this situation across the board, we should not ignore them by any means.

Mr. CUMMINGS. Anybody else have anything on it?

Mr. GRAY. I would agree. But from my understanding talking to our members, there are some generic drugs that are at the point almost now that might be worth counterfeiting from a counterfeiter's perspective. So we as an industry and as an association are working with the generic companies to look at what is the viability of putting electronic chips on those products. It is one thing to put a chip on a $100 branded item. It is another thing to put a chip on a $2 generic item. And how does that work for that generic manufacturer, because the last thing you want to do obviously is to disincent the ability of consumers to get generic drugs as well as branded drugs? So we are working as an industry to figure out what is the ability to do that with generics relative to all the things, Mr. Raber, and with the cost of these chips, all the other things that go along with the anti-counterfeiting measures. So there are particular issues regarding generics that are just beginning to get explored now.

Mr. CUMMINGS. Mr. Raber, you were laughing. Why is that?

Mr. RABER. It is really interesting because there are always, there is always a price point. It is real easy to discuss putting an RFID tag on at Oak Ridge National Labs on something that is a product related to nuclear security, and it is big things that cost lots of money, or if it is a stainless steel container that transports acid around the country that costs $5,000 for the container, it is easy to put a tag on the side of that. As my colleague says here, there is a point where you have to make a decision, does the value of putting it on outweigh the risk or not, and it really always comes back to that.

Mr. CUMMINGS. Mr. Chairman, in the interest of time, I will submit questions to the panel in writing. Thank you.

Mr. SOUDER. Mr. Ruppersberger.

Mr. RUPPERSBERGER. Just one. I just came in late, I'm sorry. I want to talk about the pedigree issue on the chain of custody. I know some States have toughened their licensing standards for distributors such as Florida, which now requires pedigree for all prescription drugs in the State. However, the FDA has delayed the ef-

fective date for national regulations requiring a pedigree until December 2006 in the hopes that an electronic track-and-trace program such as radio frequency identification will be viable. Where do you think we need to be? Do we need to wait until December 2006? Do you think Florida's plan is effective and should be used as a model for other States?

Mr. CATIZONE. Commenting from the State perspective, we're not happy that the States are embarking on this individually without national leadership, without uniform standards. But what Florida has said in a way to transition to the track-and-trace technology is they have defined normal distribution and normal distribution encompasses pretty much all the transactions that exist today between legitimate wholesalers, manufacturers and pharmacies. And Florida has then said, anything outside of that where we have seen diversion, where we have seen the problems would require an electronic pedigree.

We think that is the best approach at this point to phase in electronic pedigrees rather than coming up with a requirement for all drugs. We think the time is now. We can't wait any longer because if we do and the system becomes compromised, than every patient is going to be at risk.

Mr. GRAY. As I said, HDMA was very active in Florida, and our position, as Mr. Catizone said, as primary distributors purchasing directly through is the model that Florida has been trying and working with since 2003 on a 34-susceptible-drugs list and very successfully. To our knowledge, there's no incidence of counterfeiting in that 3-year period in Florida once they tightened down on those 34 drugs and the licensing requirements. And our position going into Florida, which ultimately was passed into law, was that pedigree would be required for those drugs that are purchased outside of the direct purchase process.

Mr. RUPPERSBERGER. What needs to be done to implement it now, the Florida plan? What's the hold up?

Mr. GRAY. They are doing regulations right now. The bill was only signed by the Governor 2 to 3 weeks ago. Some implementing regulations need to be done. And but, again, most of our companies have all been doing this on those 34 high-risk drugs, so we already know the drill, what's going to be required for information purposes. It is just now getting the States to do the formal regulations and instituting it from there.

Mr. RABER. There are a couple issues related to the industry. An organization called APC Global and some of the other organizations that are involved: The standardization of what's going to be put on an RFID tag, the standardization of what's going to be into an electronic pedigree, what that looks like; does it contain the actual NDC number that is normally associated with a drug? Does that NDC number get encrypted? What happens and what becomes part of that electronic pedigree is certainly one of the things that's up in the air. And the industry in some of the committees that exist in the different organizations is trying to work their way through that. But those are some of the obstacles that clearly exist today.

If you are using RFID in the electronic pedigree—there are means that you could do an electronic pedigree that does not have RFID. There are ways to be able to do that I would say should be

pursued rapidly as long as—as well as with the RFID coming along side of it that keep it moving forward. But there has to be some agreement on what's put in place from the product coding that occurs on the tag.

Ms. WINCKLER. From the pharmacist's perspective, we need action and we need uniformity. So we need to make sure that the protections that are in place in Iowa are as strong as those in California and Florida and Nevada and across the country. And so that requires leadership, and it needs it soon.

Mr. GRAY. I would support that. Our companies, we have national and regional, but even my regional distributors ship in multiple States and their fear is that Florida will require one element of pedigree in their chips, California another. And then they're managing multiple data bases of information.

Mr. RUPPERSBERGER. Some of the same issues we have with labelling of food throughout the country.

Mr. GRAY. Very similar. Absolutely.

Mr. SOUDER. Thank you very much. We have a vote on the basic move to the question on the rule for Internet gambling, and we have may have a vote on the rule, so we will wind this up, but we will have some additional written questions. We will try not to overwhelm you.

Some that I have to give you, some ideas here are, Mr. Raber referred to the competitive advantage of having several different technologies going here. At what point do we gain from the competitive versus having a uniform? Second, if we could get some information on what Europe does and their relative costs and why we haven't—why wouldn't we just bring that system into here? Is there a cost reason? Is there a tracking reason? Also we heard earlier, in some written testimony at least if not verbally, about ebay and flea markets or secondary sales of products, how this might affect that. Would you take those RFID's off? Is this a secure way to track?

We have had hearings in this committee on infant baby formula which has clearly been degraded and changed and altered at some risk in going to flea markets. And legislation was put in Texas, Oklahoma and a number of States to try to address that question. One that Wal-Mart was early on trying to address, putting baby formula behind the counter in some States.

Then I had some questions that I wanted to make sure got asked on what your associations were doing as far as trying to do due diligence, for example, on wholesalers, what does that mean? Are you tracking to make sure that the wholesale market is legitimate coming into the pharmacies? As you receive this price pressure from Canada in effect, the tendency is to try to find the cheapest product, and how do you kind of counter balance these type of things which also puts then legitimate above-board wholesalers at risk.

We will have a series of questions about those type of things. I'm sorry I won't get more in depth.

Mr. Gray.

Mr. GRAY. Just one item on the European. I have very close relationships with our Europe counterpart, and I will contact them in Belgium to find out what are they doing actually. I was just over

at their annual meeting, and it was news to me that they are employing it over there because I do not hear the wholesalers talking about it at their event. But I will find out for you, Mr. Chairman, exactly what is the level of BPC implementation at the wholesale level anyway in the European marketplace.

Mr. SOUDER. Also, I still am somewhat troubled, and I want to make sure this question gets in this hearing record. In the first panel, we heard high-value pharmaceuticals without really a definition or specific items of what that is which seems to me that we are putting a law in and you're guilty of a violation of this law, good luck on figuring out what you are going to be prosecuted on. And I would like some clarification on that.

Thank you very much. I have to make it over to vote. The subcommittee stands adjourned.

[Whereupon, at 11:52 a.m., the subcommittee was adjourned.]

○